bluepoint MEDICAL

Handheld Multigas / SpO_2 Monitor CapnoTrue®MG

User Manual

CapnoTrue® MG User Manual

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The information in this document is subject to change without notice.

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CE 0482

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SE519766; SE519779; SE523461; SE524086. Other patents pending

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Table of Contents

1 Introduction
1.1 Intended Use

The CapnoTrue®MG Multigas / SpO_2 Monitor is intended to provide continuous monitoring of end-tidal (et) CO_2-, N_2O- and anaesthetic agent concentrations, inspired (Fi) CO_2-, N_2O- and anaesthetic agent concentrations, functional arterial oxygen saturation (SpO_2), respiration rate (RR), pulse rate (PR) and MAC value.

The multigas analyzer is intended to be connected to a patients breathing circuit for monitoring of inspired/expired gasses during anaesthesia, recovery and respiratory care. It may be used in the operating suit, intensive care unit, patient room and emergency settings for adults, paediatric and infant patients.

The CapnoTrue® MG Multigas/SpO_2 Monitor is not intended to be used as the only means of monitoring a patient. It shall always be used in combination with other vital sign monitoring devices and/or professional human judgments of a patient's condition. The CapnoTrue® MG is intended to be used by trained and authorized health care professionals only.

1.2 Warnings

Adhere to the following warnings for safe operation of the CapnoTrue®MG Multigas / SpO_2 Monitor.

For CapnoTrue® MG in general:

⚠ *Warning: The monitor is to be operated only by trained personnel and is for attended monitoring only.*

⚠ *Warning: Do not make any clinical judgments based solely on the CapnoTrue®MG. The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. The interpretation of the measurement values should be done only by trained health care professionals.*

⚠ *Warning: The monitor should only be used for the purpose and in the manner described in this manual.*

⚠ *Warning: Explosion hazard. Do not use the monitor in the presence of flammable anaesthetic mixtures with air, oxygen, or nitrous oxide.*

⚠ *Warning: Routinely monitor the patient to make sure that the CapnoTrue®MG is functioning correctly and that the SpO_2 sensor and the IRMA AX+ analyzer are correctly placed.*

⚠ *Warning: Do not place the monitor in any position that might cause it to fall on to the patient.*

⚠ *Warning: Certain environmental and physiological conditions, medical procedures, sensor application errors and external agents may interfere with the monitor's ability to detect and display accurate measurements. (Chapter 9 provides information on possible interferences)*

⚠ *Warning: For the SpO_2 measurement, the monitor uses red and infrared light with specific fixed wavelengths. Consider that these wavelengths might influence diagnostic parameters of other optical applications. The specifications of the wavelengths used are listed in the 'Instructions for Use' of the specific sensor.*

⚠ *Warning: The monitor detects respiratory effort via changes in CO_2 concentration of exhaled air; therefore, the CO_2 measurement can be used to detect apnoea. The device however is unable to discriminate between a patient not breathing and a sensor that is disconnected from the patient circuit. Always monitor and set alarms for SpO_2 when using the CapnoTrue®MG to monitor respiratory function.*

⚠ *Warning: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the monitor is functioning correctly.*

⚠ *Warning: The use of accessories, sensors, and cables other than those specified may result in increased electromagnetic emission and/or create invalid readings of the monitor.*

⚠ *Warning: In high ambient light conditions it is required to shield the SpO_2 sensor application site with opaque material. Too much ambient light may result in inaccurate measurements.*

⚠ *Warning: Check all alarm settings and auditory alarm before use of the monitor.*

⚠ *Warning: Do not silence the audible alarm function, or decrease the audible alarm volume if patient safety could be compromised.*

⚠ *Warning: No modifications of the monitor are allowed without authorization of the manufacturer.*

⚠ *Warning: Measurements can be affected by mobile and RF communications equipment. Make sure that the monitor is used in the electromagnetic environment specified in this manual .*

⚠ *Warning: Disconnect the monitor and probes from the patient during computed tomography (CT).*

⚠ *Warning: Disconnect the monitor and probes from the patient during magnetic resonance imaging (MRI) scanning. An induced current could potentially cause burns.*

Additional warnings regarding the power supply system: To prevent the possibility of the Li-Poly battery CT-2500 from leaking, heating or explosion, observe the following precautions.

⚠ *Warning: Do not immerse the battery in water or seawater. Store it in a cool and dry environment if not used.*

⚠ *Warning: Do not discard, store or use the battery near a heat source (e.g. a fire or heater).*

⚠ *Warning: Only charge the Li-Poly battery CT-2500 while inserted in the CapnoTrue® MG monitor using the provided power supply FW 7660M/06.*

⚠ *Warning: Do not connect the positive and negative terminal with metal objects such as wire and do not transport or store the battery together with metal objects such as necklaces or hairpins as this may short-circuit the battery.*

⚠ *Warning: Do not strike, throw or trample the battery or pierce it with a nail or other sharp object.*

⚠ *Warning: Only use the Li-Poly battery Model No. CT-2500 provided with the monitor. Contact the manufacturer for replacements.*

⚠ *Warning: Only use the power supply Model No. FW 7660M/06 provided with the monitor. The use of a power supply other than this may result in hazardous situation and effect patient's safety.*

⚠ *Warning: Do not use rechargeable AA sized batteries instead of alkaline AA sized batteries to operate the device, as this may affect the function of the device.*

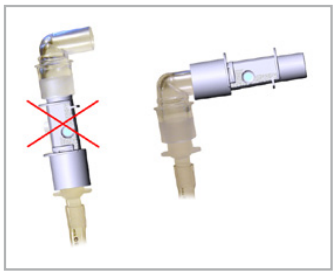
Additional warnings regarding the IRMA AX+ Analyzer:

⚠ *Warning: Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection. Used airway adapters shall be disposed of in accordance with local regulations for medical waste.*

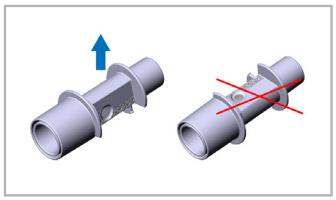
⚠ *Warning: Do not use the IRMA airway adapter (adult/paediatric) with infants as the adapter adds 6ml dead space to the patient circuit.*

⚠ *Warning: Do not use the IRMA airway adapter (infant) with adults or paediatric as this may cause excessive flow resistance.*

⚠ *Warning: Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.*



⚠ *Warning: To keep secretions and moisture from pooling on the windows, always position the IRMA AX+ analyzer in a vertical position.*



⚠ *Warning: Do not use the IRMA AX+ analyzer with metered dose inhalers or nebulised medication as this may affect the light transmission of the airway adapter windows.*

⚠ *Warning: A successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2) in the IRMA airway adapter during zeroing. Incorrect zeroing of the IRMA AX+ analyzer will result in false gas readings.*

⚠ *Warning: Replace the IRMA airway adapter if condensation occurs inside the adapter.*

⚠ *Warning: The IRMA Analyzer is not intended to be in patients contact.*

1.3 Cautions

Adhere to the following recommendations to avoid damage or malfunction of the CapnoTrue®MG Multigas / SpO_2 Monitor.

For CapnoTrue®MG in General:

Caution: Do not spray, pour, or spill any liquid on the monitor, its accessories, connectors, switches, or openings in the enclosure as this may damage it.

Caution: Do not immerse the monitor or its accessories in liquid.

Caution: Do not autoclave or steam sterilize the monitor or its accessories.

Caution: Refer to the specific 'Instructions for Use' of the used SpO_2 sensor for correct cleaning and/or sterilization.

Caution: Do not apply excessive tension to any of the monitor cables.

Caution: Do not operate the monitor outside the specified operating temperature environment.

Caution: The monitor requires no routine calibration. A basic maintenance plan conducted by qualified service personnel is recommended. Please refer to the Service Manual for detailed information.

Caution: There are no user-serviceable parts inside the CapnoTrue®MG. The cover should only be removed by qualified service personnel.

Additional cautions regarding the power supply system:

Caution: Do not use or store the Li-Poly battery at very high temperature conditions e.g. strong direct sunlight or in a heated vehicle. Under these conditions the battery can overheat, causing it to burn or its performance will degenerate and its service life will be decreased.

Caution: Do not use the Li-Poly battery in an electromagnetic environment other then specified in this manual, as this may damage the safety features of the battery and result in unforeseen danger.

Caution: If the Li-Poly battery leaks and the electrolyte gets into the eyes, immediately rinse the eyes with clean running water and seek medical assistance to prevent injury of the eyes.

Caution: If the Li-Poly battery gives off an odour, generates heat, becomes discoloured or deformed, or in any way appears abnormal during use, recharging or storage, immediately remove it from the device and stop using it.

Caution: If the Li-Poly battery terminals are dirty, clean the terminals with a dry cloth before use, otherwise a power failure or charging failure may occur due to poor connection with the device.

Caution: Discharged batteries may cause fire; tape the terminals to isolate them.

Caution: Remove the batteries if the device is to be stored or not used for a longer period of time.

Additional cautions regarding the IRMA AX+ Analyzer:

Caution: Do not immerse the IRMA AX+ analyzer in liquid.

Caution: The IRMA AX+ analyzer and the IRMA airway adapters are non-sterile devices. To avoid damage, do not autoclave these components.

Caution: Use only PHASEIN manufactured IRMA airway adapters.

1.4 Symbol Description

	Accompanied with *"Warning: Supplementary text."* within this document. Warnings indicate potential harmful conditions that may lead to injury or death.
	Accompanied with *"Caution: Supplementary text."* within this document. Cautions indicate conditions that may lead to damage to or malfunction of the device.
Note	Denoted as *"Note: Supplementary text."* within this document. Notes inform the user to relevant facts and conditions in connection with the device.
	Consult User Manual for detailed operating information.
	Consult accompanying documents for important safety-related information
	Manufacturer
	Date of manufacture
	Type BF applied part
REF	Catalogue number
SN	Serial number
P/N	Part number
LOT	Batch code
	Use by [YYYY-MM-DD] (indicates that the device should not be put into service after the date accompanying the symbol)
	Temperature limitation
	Do not re-use
	Fragile, handle with care
	Do not dispose in the consumer waste. Electrical and electronic equipment shall be collected and recycled in accordance with (Directive 2002/96/EC)
CE 0000	European Union approval (complies with 93/42/EEC Medical Device Directive)
IPXY	IP Code (International Protection Rating)

1.5 Terms and Definitions

BTPS	Body Temperature and Pressure Saturated
CapnoTrue® MG	Handheld Multigas/SpO_2 monitor developed by bluepoint MEDICAL
CO_2	Desflurane
DES	Desflurane
ENF	Enflurane
HAL	Halothane
ISO	Isoflurane
SEV	Sevoflurane
et	End-tidal expired gas concentration
Fi	Fraction of inspired gas concentration
MAC	Minimum alveolar concentration
Hb	Deoxygenated haemoglobin
HbO_2	Oxygenated haemoglobin
HME	Heat Moisture Exchanger
IR	Infrared
IRMA AX+	Infrared mainstream multigas analyzer.
Li-Poly battery	Lithium-ion polymer rechargeable battery
MDD	Medical Device Directive
MRI	Magnetic Resonance Imaging
N/A	Not applicable. Data does not apply to the configuration.
PR	Pulse rate
RF	Radio frequency
RH	Relative humidity
Rise time	Time required to achieve an increase from 10% to 90% of final value when step function change in concentration occurs at the sampling site.

RR	Respiration rate
SpO_2	Functional arterial oxygen saturation
TBD	To Be Determined. Value or property not yet decided; further investigations may be necessary.
Total system response time	Time from a step function change in gas level at the sampling site to the achievement of 90% of the final gas reading of the capnograph. Total system response time = Delay time + Rise time
USB	Universal Serial Bus
Zeroing	Ambient gas reference measurement used to establish zero concentration level for measured gasses. Zeroing needs to be performed when an offset in gas measurement values is observed, when an unspecified accuracy message is displayed and each time the IRMA airway adapter is replaced.

1.6 User Requirements

The user(s) of the monitor shall have an in-depth knowledge of gas analyzing and non-invasive monitoring of functional arterial oxygen saturation.

2 Theory of operation
2.1 Multigas measurement
2.1.1 Principle

The measurement of CO_2, N_2O and anaesthetic agents (DES, ENF, HAL, ISO, SEV) in gas mixtures with the CapnoTrue®MG is based on the fact that different gases absorb infrared light at specific wavelengths. The absorption spectra for CO_2, N_2O and different anaesthetic agents are shown in the figure below.

The gas analyzer of the CapnoTrue®MG uses the absorption peak at 4.2µm and 4.5µm for the measurement of CO_2 and N_2O respectively and five different wavelengths in the 8 – 10 µm range for anaesthetic agent measurement. Two additional wavelengths beside this absorption peak are used as reference.

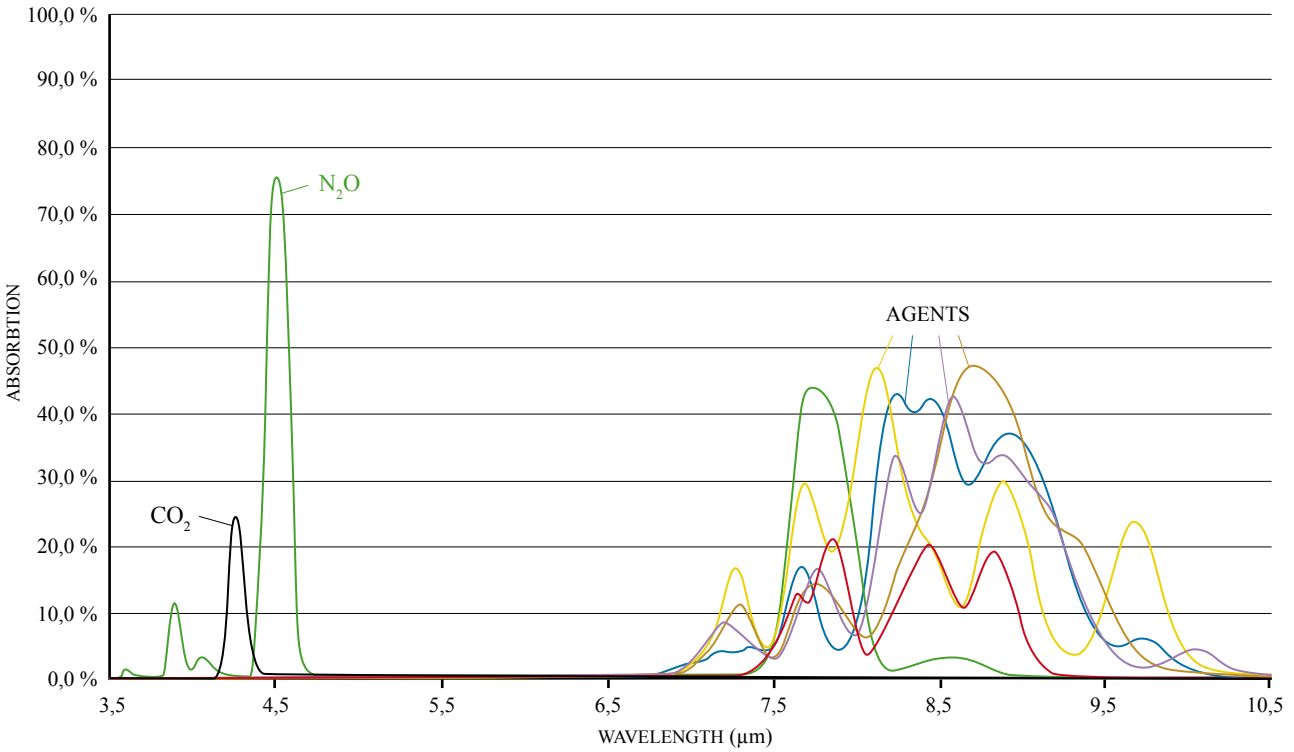


Figure 1: Gas absorption spectra

To measure the absorption of light at these wavelengths, a broadband infrared radiation source is used. The light transmitted from the infrared source passes through the gas sample and is then filtered using a set of narrow optical band pass filters. The individual filters are mounted in a rapidly rotating filter wheel that intersects the light path before the light reaches the infrared detector.

The infrared detector detects the portion of the light that is not absorbed by the gas. The amplitude of the detector output is an inverse function of the gas concentration. Thus, at a concentration of zero, the amplitude is at its maximum.

2.1.2 Method

Determining multiple gas concentration of respiratory gases is performed using the mainstream method (non-dispersive spectroscopy).

Here an airway adapter is, for example, inserted between the endotracheal tube and the Y-piece of the breathing circuit. The airway adapter has an optical window over which the infrared mainstream analyzer is positioned. The respiratory multigas measurements are obtained by continuously measuring the infrared light absorption, in the gas flow, through the optical windows.

2.1.3 Capnogram

A capnogram is a graph representing the CO_2 concentration in respiratory gasses plotted against time. The capnogram waveform is typically divided into 4 phases (Bhavani-Shankar & Philip, 2000). In the waveform below the inspiration (phase 0) is plotted

in blue and the expiration (phase I - III) in red.

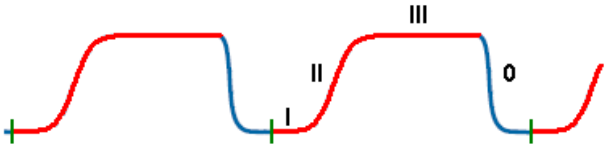


Figure 2: Normal capnogram waveform

Phase I: Baseline ($FiCO_2$)
Phase II: Positive expiration slope (alveolar gas)
Phase III: Alveolar plateau ($EtCO_2$)
Phase 0: Inspiration

A capnogram provides valuable information regarding the health situation of patients in respiratory distress.

2.1.4 MAC calculation

The MAC (Minimum Alveolar Concentration) is the concentration of an anaesthetic agent that prevents a reaction (e.g. movement) to a painful surgical stimulus (e.g. a standardized skin incision) in 50% of a population of anesthetized patients. The MAC is dependent on body temperature, atmospheric pressure and patient's age.

To be able to compare MAC values the standard 1MAC concentrations of anaesthetic agents and nitrous oxide is used. The 1MAC is based on the assumptions that the patient is 40 years old (except for Desflurane where 25 years are assumed), the body temperature is 37° and the atmospheric pressure is 760 mmHg (1 atm).

Uncorrected MAC:
The MAC value displayed at the CapnoTrue®MG is calculated by using the end-tidal (et) gas concentrations of the inhaled anaesthetics (including primary agent AA1, secondary agent AA2 and N_2O) and normalizing these to the respective 1MAC according to the following formula:

$$MAC = \frac{et\ Conc(AA1)}{1\ MAC(AA1)} + \frac{et\ Conc(AA2)}{1\ MAC(AA2)} + \frac{et\ Conc(N_2O)}{1MAC(N_2O)}$$

The 1MAC values used are according to the EN ISO 21647:2004 standard and listed in the following table:

Anaesthetic	1MAC
Halothane	0.77 %
Enflurane	1.70 %
Isoflurane	1.15 %
Desflurane	7.30 %
Sevoflurane	2.10 %
N_2O	100 %

Note: This MAC value is not corrected for ambient pressure, age, temperature or any other individual factors influencing the effect of volatile anaesthetic agents.

Age corrected MAC:
The CapnoTrue®MG features the possibility of performing a MAC age correction. Activate this mode by setting the "MAC age correction" to "On" within the SETUP MENU.

The age corrected MAC value displayed at the CapnoTrue®MG is calculated according to the following formula.

Corrected MAC value of an anaesthetic agent (all except Enflurane):

$$MAC_{corr-AA} = \frac{et\ Conc(AA)}{1MAC(AA)\ x\ 1.32\ x\ 10^{-0.00303 x age}}$$

Note: There is no clinical data available for an age correction of the MAC value of Enflurane. Therefore the MAC is not corrected for Enflurane even if this function is selected.

Corrected MAC value of nitrous oxide:

$$MAC_{corr-N2O} = \frac{et\ Conc(N_2O)}{100\ x\ 1.32\ x\ 10^{-0.00347 x age}}$$

Total Age Corrected MAC value:

$$MAC_{corr-AA} = MAC_{corr-AA1} + MAC_{corr-AA2} + MAC_{corr-N2O}$$

This calculation is based on the study performed by Edmond I Eger II which was published in the article „Age, minimum alveolar anaesthetic concentration and minimum alveolar anaesthetic concentration-awake" (Anesth Analg 2001, 93: 947-53).

Note: This MAC value is not corrected for ambient pressure, temperature or any other individual factors influencing the effect of volatile anaesthetic agents.

2.2 SpO_2 measurement

SpO_2 measurement is performed in transmission mode. The SpO_2 sensor consists of emitters which pass red and infrared light through peripheral sites such as a finger, toe or ear to a light-sensitive detector.

For both wavelengths the change in absorption is continuously measured. In this way the pulsatile signal due to the arterial blood alone is extracted, excluding the offset due to absorption by venous blood, skin, bone, muscle and fat.

This signal is used to determine the functional arterial oxygen saturation (SpO_2) based on the fact that the amount of absorbed infrared light and red light is different for oxygenated haemoglobin (HbO_2) and deoxygenated haemoglobin (Hb).

The amount of red and infrared light received is compared and the percent of haemoglobin molecules bound with oxygen molecules calculated:

$$SPO_2 = \frac{HbO_2}{HbO_2 + Hb}$$

These measurement values are continuously displayed as a waveform (plethysmogram) and also used to determine the pulse rate. Note that the pulse oximeter equipment is calibrated to display the functional oxygen saturation.

Certain physiological conditions, medical procedures, and external agents may interfere with the monitor's ability to detect and display accurate SpO_2 measurements (see chapter 9.2 for detailed information).

3 Product overview

3.1 Mainstream multigas monitor and Pulse Oximeter – CapnoTrue®MG

The CapnoTrue®MG is used together with an IRMA AX+ analyzer, an IRMA airway adapter and an application appropriate SpO_2 sensor.

Power is delivered via either the provided power supply, a rechargeable Li-Poly battery or 4 x AA batteries.

Mainstream multigas monitoring is performed with the IRMA AX+ analyzer. This key technology sets new standards in multigas measurement and provides reliable, safe and easy anaesthetic agent monitoring.

Key features of CapnoTrue®MG:

- Innovative micro-optic technology
- Direct mainstream measurement without time delay
- Warm-up time < 20seconds full specification
- Maintenance and calibration-free technology
- Adult/paediatric and infant IRMA airway adapters available
- Self-explanatory, ergonomic operating functions facilitate intuitive operation
- The colour information display, as well as the simple information structure, support quick decisions and a rapid user reaction in critical situations
- Leading-edge power management with standard alkaline batteries, Li-Poly batteries or medical external power supply (or combination)
- Wide range of high-quality SpO_2 sensors available
- 2 years warranty

3.2 Device components

3.2.1 IRMA AX+ analyzer

The IRMA AX+ analyzer is an ultra compact measurement device for mainstream multigas measurement with the CapnoTrue®MG. As all necessary calibration constants are stored within each IRMA AX+ analyzer, the analyzer can be replaced without the need for recalibration.

The analyzer has a rugged mechanical design providing reliable shock resistance.

Figure 3: IRMA AX+ analyzer with airway adapter

To perform gas measurements, the IRMA AX+ analyzer requires an airway adapter. The IRMA AX+ analyzer connects in place on top of the IRMA airway adapter. This airway adapter is, for example, inserted between the endotracheal tube and the Y-piece of the breathing circuit.

Respiratory multigas measurements are obtained by continuously measuring the infrared light absorpti-

on, through optical XTP™ windows, in the gas flow through the adapter.

3.2.2 IRMA airway adapter

The IRMA airway adapter is designed as a single-patient-use disposable product and is available as:

- IRMA airway adapter (adult/paediatric) for patients over 1 year of age or 10kg in weight.
- IRMA airway adapter (infant) for patients up to 1 year of age or 10kg in weight.

The IRMA airway adapter (infant) has specially designed connectors for minimizing the dead space and can be used on very small patients.

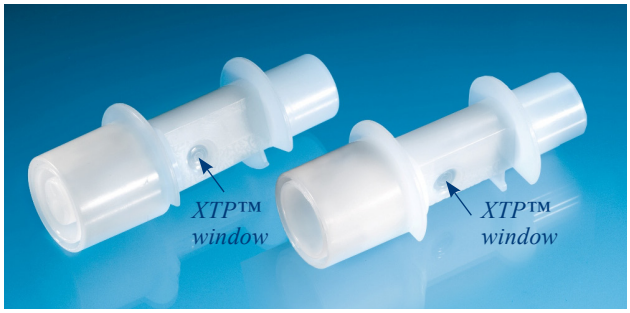


Figure 4: IRMA airway adapters: Infant (left) and Adult/Paediatric (right)

As the airway adapter is positioned directly in the airway, its performance can be affected by water vapour, patient secretions or nebulised medications that can accumulate on the adapter's windows.

The water vapour can condense on the surface of the adapter windows in the format of small discrete water droplets. This condensation can affect light absorption through the windows, thus affecting the precision of the measurement.

The XTP™ windows of the IRMA airway adapter therefore have special features that prevent a decrease in performance when vapour is present. Using the latest advances in material technology they are designed to provide a window minimizing the impact of water vapour on light transmission.

For optimal results, the airway adapter shall not be placed between an endotracheal tube and an elbow, as this may allow patients secretions to block the adapter window.

3.3 SpO_2 Sensors

Bluepoint MEDICAL supplies a large variety of disposable and reusable SpO_2 sensors for use with the CapnoTrue®MG.

Depending on the sensor type and model, their application ranges from adults to neonates, providing application specific features and design.

The SoftCap® Sensor is typically used for adult applications and the SoftWrap® Sensor for infant and neonatal applications (see figure 7). Other sensors are available upon request.

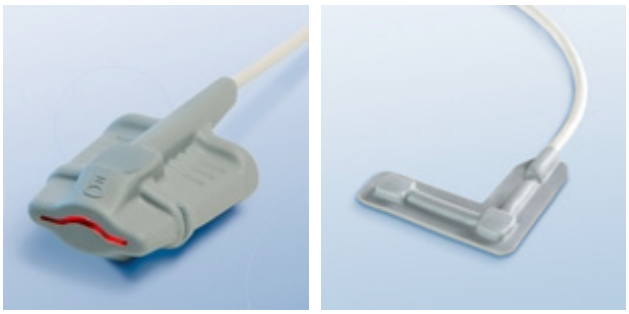
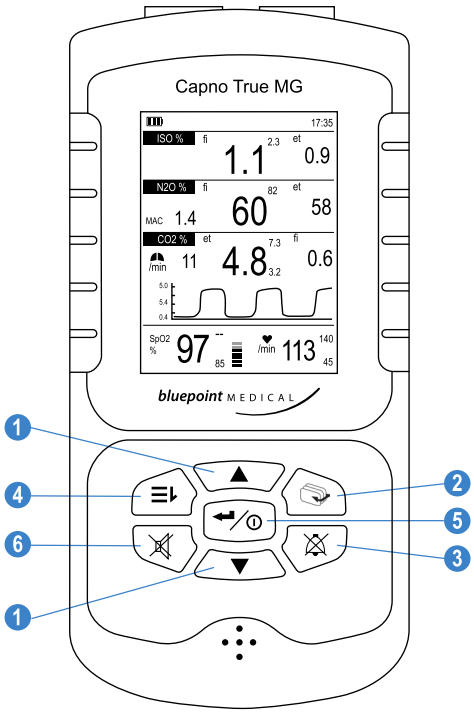


Figure 5: SpO_2 sensor SoftCap® (left) and SoftWrap® (right)

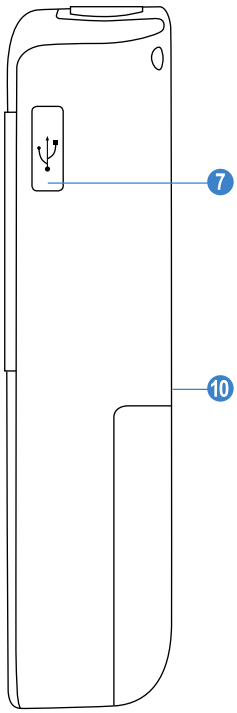
All sensors operate in transmission mode. The light source emits red and infrared light with wavelengths of 660nm and 905nm respectively at a typical radiant power of 3.5mW.

The SpO_2 sensor is applied to peripheral areas of the body such as finger tips and toes for adults, and paediatrics, and the foot or palms for infants and neonates.

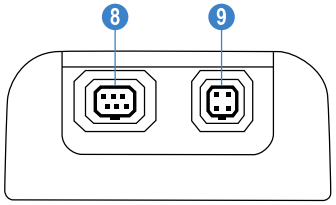
4 Exterior View, Controls and Connectors



Front view



Side view



Top View

No.	Symbol	Feature/Button	Function
1	▲▼	Arrow buttons (up/down)	Multifunction buttons used for: 1. Scrolling through menu items 2. Increasing/decreasing parameters 3. Shortcuts to volume/brightness control during monitoring
2		Display mode	Toggles between various display modes. Shortcut to return to display mode during menu mode.
3		Alarm silenced/reset	1. The audible alarm can be silenced for a maximum period of two minutes. Optical alarm remains activated. 2. To reset alarms press and hold the button for approx. 3 seconds.
4		Menu	Menu selection. Shortcut to return to the previous menu level during menu mode.
5		On/Off and ENTER button	1. To turn on the device: press and hold the button briefly. 2. To turn off the device: press and hold the button for approx. 3 seconds. 3. To confirms selection at the device: press and hold the button briefly while the device is switched on.
6		Pulse tone	Turns pulse tone on/off
7		USB	USB 2.0 interface
8		SpO_2 Sensor port	Port to connect the SpO_2 sensor

▶

9		Multigas Mainstream port	Port to connect the IRMA AX+ analyzer
10		Power input	Port to connect the external power supply (100-240V AC / 50-60Hz, Model No. FW 7660M/06)

5 Preparation for Use
5.1 Selecting Power Supply

Power is supplied to the monitor either via external power supply, rechargeable Li-Poly battery, or 4 x AA alkaline batteries.

5.1.1 Power Supply

The external power supply (100-240V AC / 50-60Hz, Model No. FW 7660M/06) is used for continuous operation of the monitor and to charge the Li-Poly battery.

Connecting the power supply (see figure 8):
1. To operate by mains, connect the power supply cable into the power input socket located at the back of the device.
2. Ensure that the correct power supply plug is connected to the power supply. It can be exchanged by pressing the release button (2.1) on the power supply. As standard the device is supplied with a European and United Kingdom plug. Additional plugs are available upon request.
3. Connect the power supply to an AC outlet.

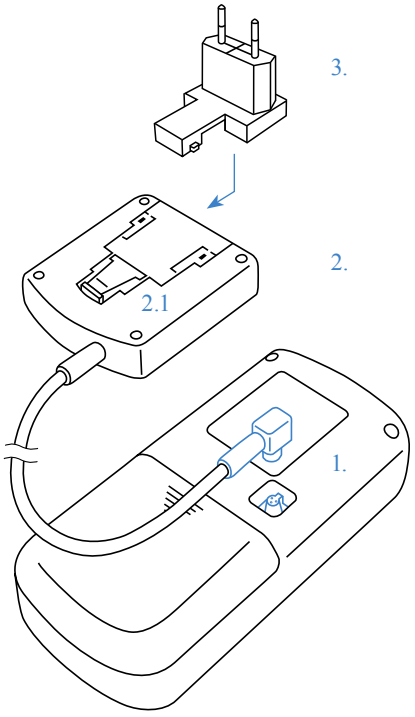


Figure 6: Connect the power supply

⚠ *Warning: Only use the power supply Model No. FW 7660M/06 provided with the monitor. The use of a power supply other than this may result in hazardous situation and effect patient's safety.*

5.1.2 Rechargeable Li-Poly Battery or AA Alkaline Batteries

For convenient monitoring in emergency medicine or during patient transport the monitor can be powered by the rechargeable Li-Poly battery (3.7 V / 2500 mAh, Model No. CT-2500) or with 4 x AA alkaline batteries.

When the device is connected to an AC outlet the Li-Poly battery will begin recharging. This is represented by the three segments of the battery level indicator illuminating in sequence. When the Li-Poly battery is completely recharged the three segments of the battery level indicator will be displayed fully.

Note: The charging function is not available at the battery contacts of the 4 x AA alkaline batteries.

Battery Installation (see figure 9):
1. Slide down the cover of the battery compartment on the rear panel of the device.
2. Insert four alkaline batteries (1.5V, AA), ensuring the correct orientation in accordance with the polarity markings.
3. Alternatively, insert the rechargeable Li-Poly battery (Model No. CT-2500), orientated according to the guiding grooves.
4. Slide the battery-compartment cover back into its initial position to close.

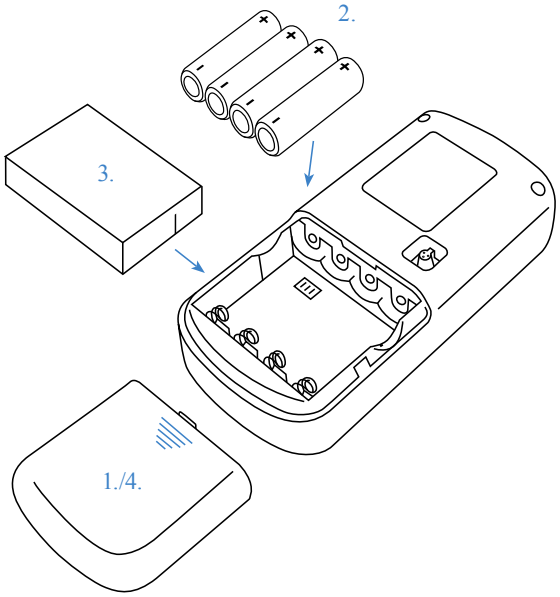


Figure 7: Insert a Li-Poly battery or 4 x AA alkali batteries

⚠ *Warning: Only charge the Li-Poly battery CT-2500 while inserted in the CapnoTrue®MG monitor using the provided power supply FW 7660M/06.*

Caution: Do not dispose the Li-Poly battery or the alkaline batteries in the consumer waste, if they are empty or can no longer be recharged. Batteries may contain substances which are harmful to the environment and to the health. Please dispose the batteries at the available battery collecting sites or the recycling yards of the municipalities. Please only dispose discharged batteries into the designated containers. Tape the terminals of the Li-Poly batteries at the poles before disposing.

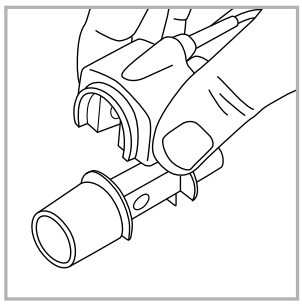
Caution: Remove the batteries if the device is to be stored or not used for a longer period of time.

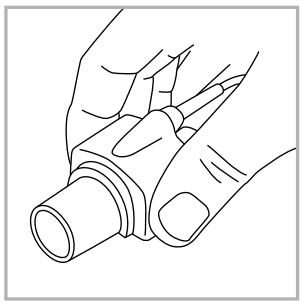
5.2 Connecting Sensors to the CapnoTrue®MG

5.2.1 IRMA AX+ Analyzer

Inspect the IRMA AX+ analyzer and connector cables for any external damage.

Insert the connector of the IRMA AX+ analyzer into the Multigas Mainstream port located on the top edge of CapnoTrue®MG. Secure the IRMA AX+ analyzer on top of the IRMA airway adapter. It will click into place when correctly seated.





Warning: Do not use the IRMA airway adapter (adult/paediatric) with infants as the adapter adds 6ml dead space to the patient circuit.

Warning: Do not use the IRMA airway adapter (infant) with adults or paediatric as this may cause excessive flow resistance.

Caution: Use only PHASEIN manufactured IRMA airway adapters.

5.2.2 SpO_2 Sensor

Inspect the SpO_2 sensor and connector cables for any external damage.

Insert the SpO_2 sensor cable into the SpO_2 sensor port located on the top edge of the device, ensuring correct orientation of the sensor connector and the port.

5.3 Visual Check

Before commencing operation, ensure that the device, its power supply and sensors are not damaged.

Warning: Do not use sensors, cables or lines that appear to be damaged. Do not use sensors when optical components are exposed. Do not use a device that appears damaged. Replace the monitor immediately in cases of visible damage.

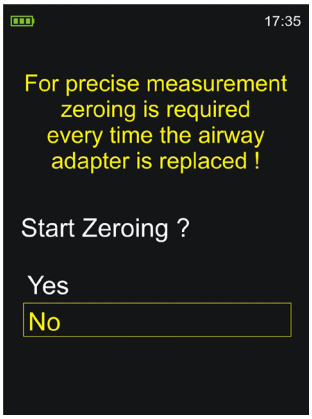
Warning: Ensure that the speaker is clear of any obstruction and that the speaker holes are not covered. Failure to do so could result in an inaudible alarm tone.

Warning: Check the compatibility of the monitor, probe and cable before use. Incompatible components can result in degraded performance.

5.4 Switching on the Device

Press and hold the ON/OFF button ↵/⏻ briefly until an opening "welcome screen" appears. The power-on self-test is successfully completed after a single loud tone sounds.

For precise measurement zeroing is required every time the airway adapter is replaced. The user is therefore asked to perform a zeroing before commencing monitoring.



Before performing zeroing refer to chapter 11.4 for detailed information.

If the airway adapter has not been replaced and there is no indication that zeroing is required, select "NO" to start measurements.

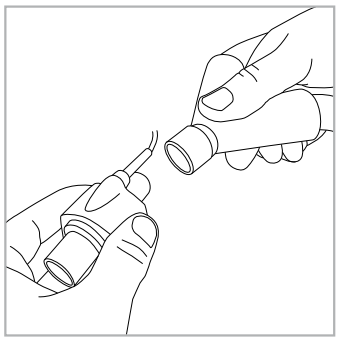
5.5 Connecting the Sensors to the Patient
5.5.1 IRMA AX+ Analyzer

A green LED indicates that the IRMA AX+ Analyzer is powered and ready for use. Perform the following tests prior to connecting the IRMA AX+ Analyzer to the patient circuit:

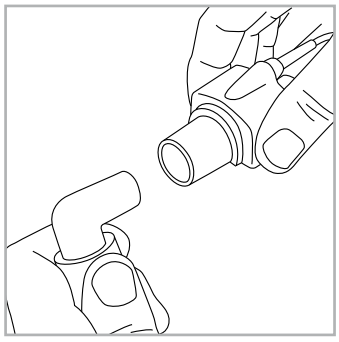
1. Breath into the airway adapter and check that valid CO_2 waveforms and values are displayed by the monitor.
2. Remove the airway adapter and wait for 5 seconds.
3. Check that the airway adapter alarm is displayed and that the LED at the IRMA AX+ Analyzer shows a flashing red light.

⚠ *Warning: Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection. Used airway adapters shall be disposed of in accordance with local regulations for medical waste.*

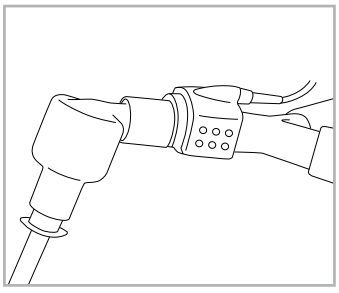
Connect the IRMA airway adapter to the patient circuit:



1. Connect the 15 mm male connector of the IRMA airway adapter to the breathing circuit Y-piece.



2. Connect the 15 mm female connector of the IRMA airway adapter to the endo-tracheal tube with or without an angled connector.

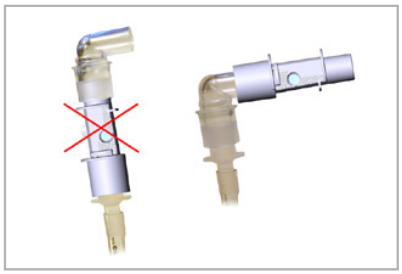


Alternatively, connect a HME (Heat Moisture Exchanger) between the patient's endo-tracheal tube and the IRMA AX+ analyzer. Placing a HME in front of the IRMA AX+ analyzer protects the airway adapter from secretions and effects of water vapour and eliminates the need of changing the adapter. It allows free positioning of the IRMA AX+ analyzer as well.

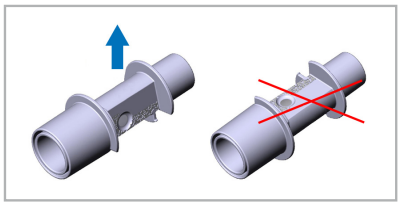
3. Perform the tightness check of the patient circuit with the IRMA AX+ analyzer connected on the airway adapter.

4. When connecting the IRMA AX+ analyzer to an infant patient circuit it is important to avoid a direct contact between the analyzer and the infant's body. If, for whatever the reason, the IRMA AX+ analyzer is in direct contact with any parts of the infant's body an insulation material shall be placed between the analyzer and the body.

⚠ *Warning: Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.*



⚠ *Warning: To keep secretions and moisture from pooling on the windows, always position the IRMA AX+ analyzer in a vertical position.*

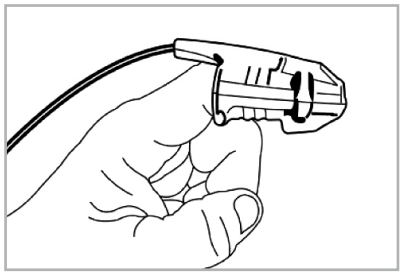


⚠ *Warning: Replace the adapter if condensation occurs inside the airway adapter.*

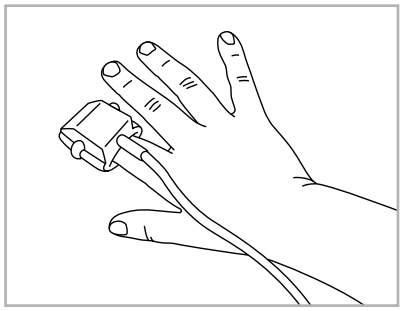
⚠ *Warning: The IRMA Analyzer is not intended to be in patients contact.*

5.5.2 SpO_2 Sensor

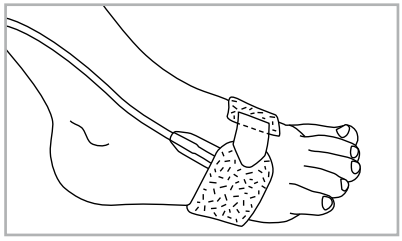
1. Refer to the sensor 'Instructions for Use' to determine if an appropriate sensor is being used, and if it is applied correctly.



Adult



Paediatric



Neonatal

2. Confirm that all connections have been made correctly by verifying an actual SpO_2 waveform on the monitor display.

⚠ *Warning: Avoid application of the SpO_2 sensors to oedematous or fragile tissue.*

⚠ *Warning: Do not use the SpO_2 sensor if it is damaged. Use of a damaged sensor could cause patient injury or equipment failure.*

⚠ *Warning: Excessive patient motion, excessive ambient light, electromagnetic interference, dysfunctional haemoglobin, low perfusion, intravascular dyes, finger nail polish and long or artificial finger nails may affect the sensor performance and the accuracy of the measurement.*

⚠ *Warning: Do not autoclave the SpO_2 sensor.*

⚠ *Warning: For the SpO_2 measurement, the monitor uses red and infrared light with specific fixed wavelengths. Consider that these wavelengths might influence diagnostic parameters of other optical applications. The specifications of the wavelengths used are listed in the 'Instructions for Use' of the specific sensor.*

Caution: Depending on the sensor model, specifications can differ. For sensor specific information on wavelengths and radiant power, please refer to the 'Instructions for Use' provided with your SpO_2 Sensor.

Caution: For further instructions, warnings and precautions refer to the 'Instructions for Use' provided with the SpO_2 Sensor.

5.6 Commencing Monitoring

Once the sensors are connected and correctly positioned on the patient, monitoring begins automatically. An audiovisual alarm appears, if any of the sensors are disconnected from the device.

The CapnoTrue®MG can be reset to the start-up configuration by resetting the alarms (refer to Chapter 7.6).

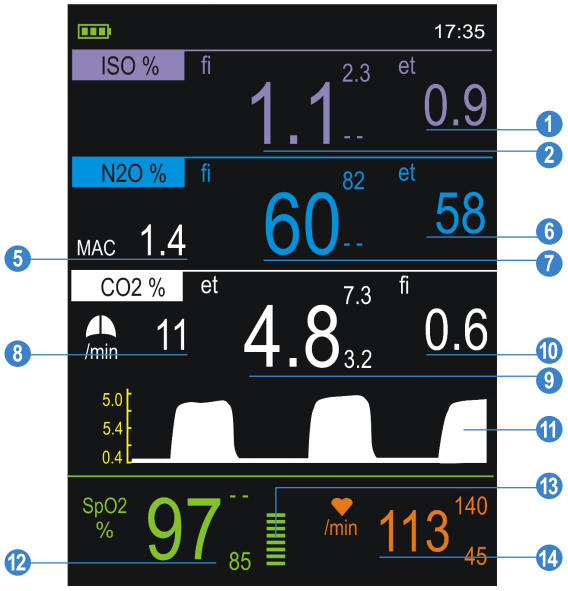
5.7 Switching off the Device

Press and hold the on/off button ↵/⏻ for approx. 3 seconds to switch off the device. The CapnoTrue®MG will also power off automatically after 5 minutes when not in use.

6 Display Modes and Displayed Data
6.1 Toggling Between Display Modes

The operator can toggle between various display modes by pressing the button.

DISPLAY 1



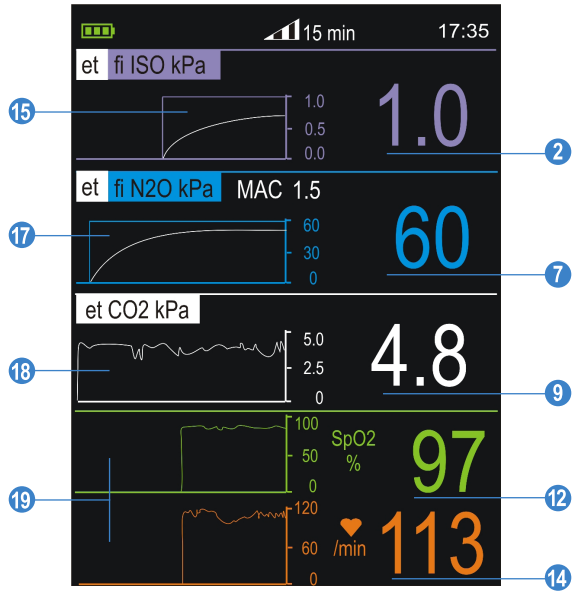
Standard – one anesthetic agent

Standard – two anesthetic agents

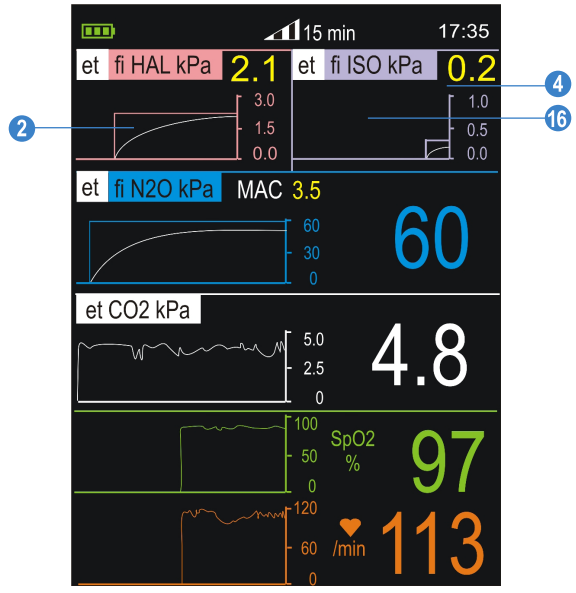
1	End-tidal expired primary anaesthetic gas concentration in vol% or kPa
2	Inspired primary anaesthetic gas concentration in vol% or kPa
3	End-tidal expired secondary anaesthetic gas concentration in vol% or kPa
4	Inspired secondary anaesthetic gas concentration in vol% or kPa
5	MAC value
6	End-tidal expired N_2O gas concentration in vol% or kPa
7	Inspired N_2O gas concentration in vol% or kPa
8	Respiration rate in breaths per minute
9	End-tidal expired CO_2 gas concentration in vol %, kPa or mmHg
10	Inspired CO_2 gas concentration in vol %, kPa or mmHg
11	CO_2 waveform (Capnogram) The default setting of the amplitude scale is Auto scaling. Here the reading is automatically adjusted to the signal strength; therefore, a waveform with strong amplitude should be visible at all times. The scale however can also be defined by the user (refer to chapter 8.1.3).
12	Functional blood oxygen saturation in units of percent SpO_2
13	Bar graph for pulse amplitude: Indicates the dynamic pulse amplitude and rate. As the detected pulse becomes stronger, more bars light with each pulse. The reverse is true for weak pulses.
14	Pulse rate in beats per minute
15	Combined et and Fi trend waveform of the primary anaesthetic gas
16	Combined et and Fi trend waveform of the secondary anaesthetic gas
17	Combined etN_2O and FiN_2O trend waveform
18	Combined etCO_2 and FiCO_2 trend waveform
19	SpO_2 and pulse rate trend waveform

DISPLAY 2 – 4

15 min, 1 h and 6 h Trend, parallel to ongoing measurement

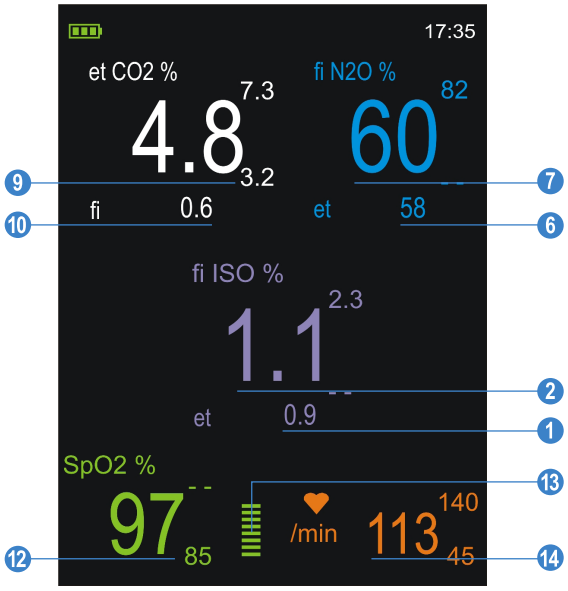


15 min Trend – one anesthetic agent



15 min Trend – two anesthetic agents

DISPLAY 5



Numeric – one anesthetic agent

Numeric – two anesthetic agents

The small numbers on the right hand side of the measurement value of a parameter indicate the upper and lower alarm limits. In all displays the measurement value, alarm limits, curve, name and unit of each parameter are displayed in the same colour. The IRMA AX+ analyzer automatically detects anaesthetic agents. If more than one agent is present, the according section will split and display both the primary and the secondary agent.

6.2 Symbols and Indicators

No.	Symbol/ Indicator	Function
1		**Battery level indicator** The three segments represent the battery charge level. The symbol flashes yellow when the battery capacity is low. During charging of the Li-Poly battery, the three segments of the indicator are illuminated in sequence.
		Power supply indicator The power supply is connected and no batteries are inserted.
2		**Alarm silence indicator** The audible alarm can be silenced for a maximum period of two minutes. Optical alarm remains activated.
3		**Pulse tone off**
4		**Memory full indicator** The device's memory for measurement data is full. No new data can be stored. Old data can be erased or are overwritten.
5	15 min	**Trend window indicator** The indicator is only displayed in the trend screens (display 2 – 4) and displays the window size of the trend data. (15 min, 1 h or 6 h)
6		**Real-Time Mode indicator** The device is operated in the Real-Time mode. Data is available at the USB port
7	17:35	**Current time**, displayed in 12h or 24h format.
8	/min	**Respiration rate**, displayed in breaths per minute.
9	/min	**Pulse rate**, displayed in beats per minute.
10		The colour of the bar graph is an indicator of the signal quality **Green**: good signal quality, very accurate measurement **Yellow**: average signal quality, measurement may be inaccurate **Red**: poor signal quality, unreliable measurement

6.3 Pulse Tone

During monitoring a pulse beep is sounded for every detected pulse. The pitch of the pulse tone is dependent on the measured SpO_2 value. A higher pitch is indicative of higher oxygen saturation.

The pulse tone volume can be adjusted under the menu item 'Volume'. The pulse tone can be also silenced using the button. Pressing this button for a second time will reactivate the pulse tone.

7 Alarms
7.1 Alarm Priority and Appearance

The CapnoTrue®MG differentiates between alarms of high, medium and low priority.

An alarm of higher priority will always overlay alarms of respective lower priority. Vice versa, an alarm of high priority cannot be silenced by an alarm of lower priority. In this way the CapnoTrue®MG will always display the alarm with the highest priority, if more than one alarm condition exists at the same time.

7.2 Audible Alarm Volume

The alarm volume is not adjustable; however, it is possible to silence the alarm for a period of two minutes using the ⊠ button. It has an audibility of at least 55 dB (A) in 1 meter distance of the device.

Alarm Priority and Appearance

Priority Level	Audio Signal Sequence (repeatedly)	Visual Alarm	Condition
High (Warning)	*5 tone beep + 2 seconds pause + 5 tone beep and 3 seconds pause*	*Red and !!!*	For potentially life-threatening situations
Medium (Caution)	*3 tone beep and 5 seconds pause*	*Yellow and !!*	For potentially serious problems that are presumed to be not life threatening
Low (Advisory)	*2 tone beep and 16 seconds pause*	*Yellow and !*	Advisory alarms

7.3 Default Alarm Limits

Limit	Range	"Default"	Unit
Et CO_2 High	0.1..9.9 / off	7.3	%
Et CO_2 Low	off / 0.1..9.9	3.2	%
Fi N_2O High	1..82 / off	82	%
Fi N_2O Low	off / 1..82	off	%
Fi HAL High	0.2..25.0 / off	1.5	%
Fi HAL Low	off / 0.2..25.0	off	%
Fi ENF High	0.2..25.0 / off	3.4	%
Fi ENF Low	off / 0.2..25.0	off	%
Fi ISO High	0.2..25.0 / off	2.3	%
Fi ISO Low	off / 0.2..25.0	off	%
Fi SEV High	0.2..25.0 / off	4.2	%
Fi SEV Low	off / 0.2..25.0	off	%
Fi DES High	0.2..25.0 / off	12.0	%
Fi DES Low	off / 0.2..25.0	off	%
$FiCO_2$ High	0.1..9.9 / off	1.2	%
RR High	4..150 / off	off	/min
Apnoea	20, 40, 60	20	sec
SpO_2 High	1..99 / off	off	%
SpO_2 Low	off / 1..99	85	%
PR High	1..250 / off	140	/min
PR Low	off / 1..250	45	/min

7.4 Limit Alarm

The table below shows the limit alarms, alarm conditions and priority of the CapnoTrue®MG. Depending on the priority of the alarm the respective measurement value will change colour and an audible alarm sounds.

Limit Alarm	Condition	Priority
$EtCO_2$ High	$EtCO_2$ value above set alarm limit	Medium
$EtCO_2$ Low	$EtCO_2$ value below set alarm limit	Medium
$FiCO_2$ High	$FiCO_2$ value above set alarm limit	Medium
FiN_2O High	FiN_2O value above set alarm limit	Medium
FiN_2O Low	FiN_2O value below set alarm limit	Medium
FiAgent High	FiAgent value above set alarm limit	Medium
	FiAgent value above set alarm limit > 2 min	High
FiAgent Low	FiAgent value below set alarm limit	Medium
Agent mixture	MAC of mixed agents < 3MAC	Low
	MAC of mixed agents ≥ 3MAC	Medium
RR High	Respiratory rate above set alarm limit	Medium
Apnoea !!	No breath detected within set terms (if ≤ 1min)	Medium
Apnoea !!!	No breath detected within set terms (if > 1min)	High
SpO_2 High	SpO_2 value above set alarm limit in the standard mode	Low
SpO_2 Low	SpO_2 value below set alarm limit	Medium
PR High	Pulse rate above set alarm limit	Medium
PR Low	Pulse rate below set alarm limit	Medium

7.5 Alarm Messages

The table below presents the alarm messages, alarm condition and priority of the CapnoTrue®MG. The colour of the alarm message and its audible alarm depend on the priority of the alarm message.

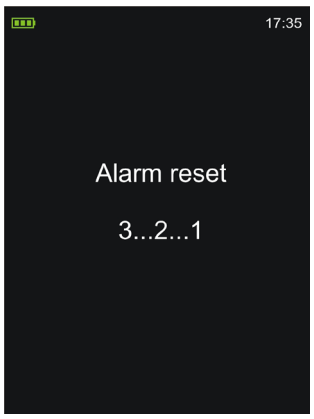
⚠ *Warning: The monitor detects respiratory effort via changes in CO_2 concentration of exhaled air; therefore, the CO_2 measurement can be used to detect apnoea. The device however is unable to discriminate between a patient not breathing and a sensor that is disconnected from the patient circuit. Always monitor and set alarms for SpO_2 when using the CapnoTrue®MG to monitor respiratory function.*

Alarm Messages	Condition	Priority
Bad signal quality!!!	Poor-quality pulse signal, for example as a result of low perfusion	High
No Analyzer!	No connection to the mainstream IRMA AX+ analyzer	Low
Check Adapter!	The mainstream IRMA adaptor is dirty, not positioned correctly etc.	Low
CO_2 Over range!	Measured CO_2 concentration is outside of the specified accuracy range	Low
N_2O Overrange!	N_2O outside specified accuracy range	Low
Anesthetic agent overrange!	At least one agent outside specified accuracy range	Low
Temperature overrange!	Internal temperature outside operating range	Low
Ambient pressure overrange!	Ambient pressure outside operating range	Low
Zeroing required!	Zero reference calibration required	Low
Unspecified accuracy!	Agent identification and concentrations are unreliable	Low
No SpO_2 Sensor!	No connection to the SpO_2 sensor	Low
SpO_2 Probe off!	SpO_2 sensor is connected to the device, a signal was detected and then the finger has been removed/slipped off	Low
Excess light!	High ambient light sources near the SpO_2 sensor, e.g. surgical lights	Low
Battery low!	Low battery level at start up results in error message and dysfunction. Low battery level during monitoring results in audible alarm and battery indicator to flash yellow for 3 minutes. Thereafter the indicator turns red, the battery low message appears and the device switches off.	Low

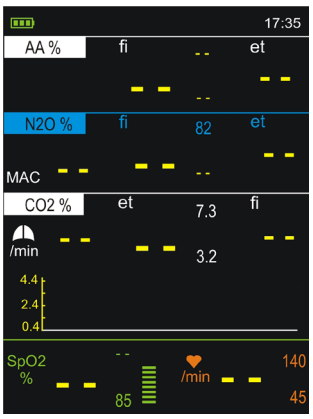
7.6 Resetting of Alarm Signals

Once triggered, an alarm will only be reset if the cause of the alarm has been resolved. Individual alarm limits can also be completely deactivated if required.

Alarm signals can be reset by pressing and holding the ⊠ button for 3 seconds. If the initial condition for the warning is still present after resetting the warning signals, the warning will return immediately. In case of the alarm signals “No SpO_2 Sensor !”, “SpO_2 Probe off !” and “No Analyzer !” the device reverts to the on-position. Parameters which have been set by the user will remain once an alarm is reset.



Press and hold button ⊠



Display after reset of alarms

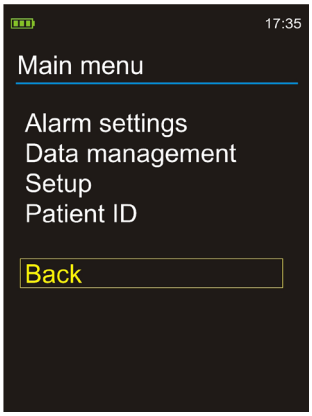
8 Menu Structure

Alarm settings	CO_2 , RR, Apnoea
	SpO_2 , PR
	Anesthetics (N_2O, DES, ENF, HAL, ISO, SEV)
Data management	Stored data
	Stored alarms
	Delete all data
Setup	Volume
	Brightness
	SpO_2 Averaging
	Date - Time
	MAC correction
	CO_2 Unit
	N_2O and agents unit
	Language
	y-Scale (CO_2, N_2O, Agents)
	CO_2 Time base
	Real-Time mode
	Gas compensation
	Zeroing
	Service
Patient ID	Patient ID No.

8.1 Main Menu

Navigating the Menu

Use the ▲▼ buttons to scroll through menu items. The currently selected menu item is highlighted by a coloured frame. Press the ↵/⏻ button to confirm your selection. Select the menu item ‘Back’ to return to the previous menu level. Alternatively use the menu button ☰↓ as shortcut for “Back”.



All important and frequently used settings are accessible through the main menu, which can be accessed by pressing the ☰↓ *button.*

Entering Data

In some submenus it is possible to adjust a certain parameter. In this case the parameter can be increased or decreased using the ▲▼ buttons. The value will increase or decrease more quickly when the respective button is held down. Press the ↵/⏻ button to confirm the new value.

Exiting Menu and Returning to Display

Press the display button at any time, in any menu to return immediately to the monitoring display. If no button has been pressed for more than 30 seconds, the device will automatically return to the monitoring screen.

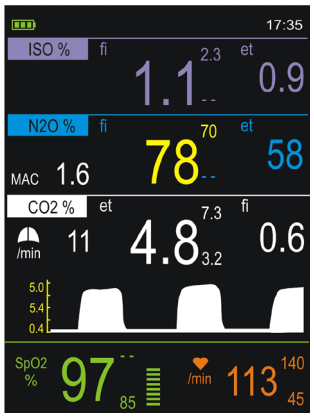
8.1.1 Submenu: Alarm Settings

General Information

The CapnoTrue®MG alarm limits for $etCO_2$, $FiCO_2$, FiN_2O, FI anaesthetic agents, SpO_2, respiration rate and pulse rate can be set individually. The current alarm limits are displayed as small numbers on the right hand side of the measurement value. If a measured value either exceeds the upper limit or falls below the lower limit, visual and audible alarms will be triggered immediately.

Visual alarm

When an alarm has been triggered the critical value will flash and turn yellow together with the violated alarm limit.

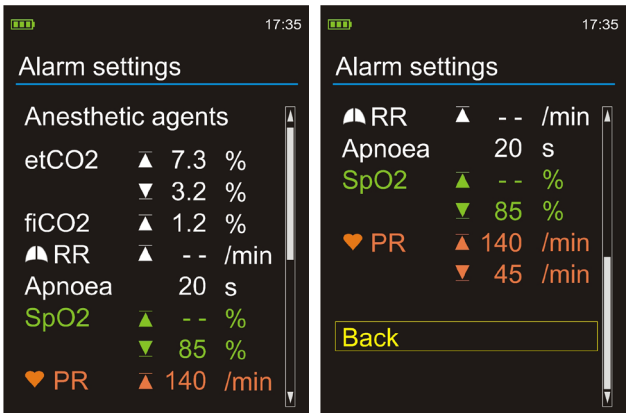


Visual alarm which was triggered by a violation of the upper N_2O alarm limit

An alarm will also be triggered if the SpO_2 sensor is removed from the patient, the SpO_2 signal quality remains poor over a longer period of time or the IRMA airway adapter is removed. This is also the case if the SpO_2 sensor or the IRMA AX+ analyzer is disconnected from the device.

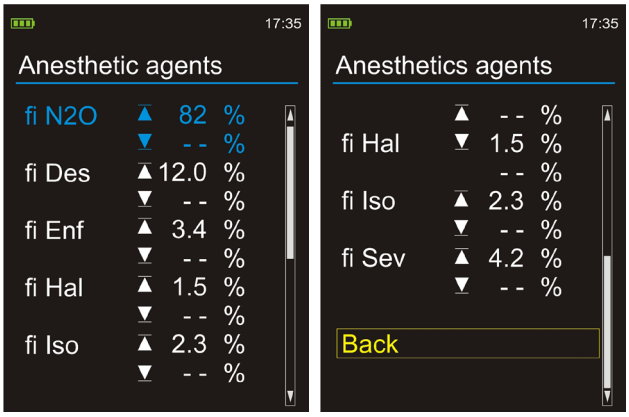
Adjusting Settings

Use the Alarm Settings menu to set the upper and lower alarm limit of $EtCO_2$, SpO_2, respiration rate, pulse rate and $FiCO_2$. Select "- -" to deactivate the respective alarm limit.



Selection with ▲▼ buttons /confirmation with ↵/⏻ button

"Apnoea" represents the lower alarm limit of the respiration rate. If no breath is detected within the set time, the apnoea alarm is activated. After restarting the device, the default alarm limits will be reset.



Enter "Anesthetic agents" to set upper and lower Fi limits for N_2O and the agents Desflurane, Enflurane, Halothane, Isoflurane and Sevoflurane.

8.1.2 Submenu: Data Management

8.1.2.1 Recording Data

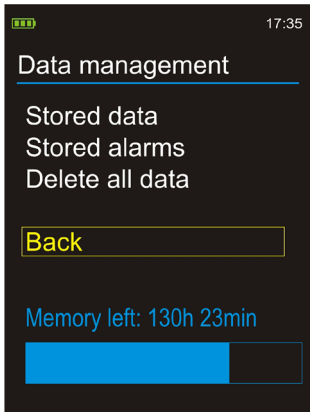
The CapnoTrue®MG device can store more than 150 hours of monitoring data. Each individual data set, regardless of its actual length, uses at least 40 minutes of memory space. A new data set is generated automatically each time the device is turned on or the current Patient ID is changed. This is also the case if the date or time of the device is adjusted via the setup menu.

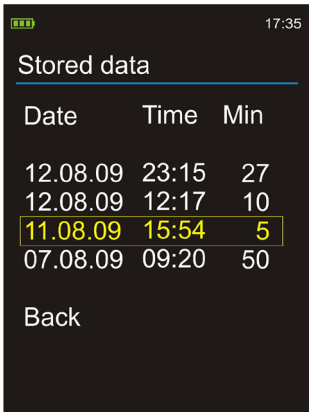
When the device is turned off or the current Patient ID is changed, all of the measurements that were taken are automatically stored in the devices memory, together with the respective alarm limits, patient ID, date and time.

The device warns the user when the memory is almost full by displaying the ⇨ symbol. If the memory is full the oldest data set is overwritten upon confirmation by the user. Stored data sets can be retrieved and erased under the menu item “Data management”. The data sets can also be downloaded on PC with the user-friendly CapnoTrue®MG PC-Software.

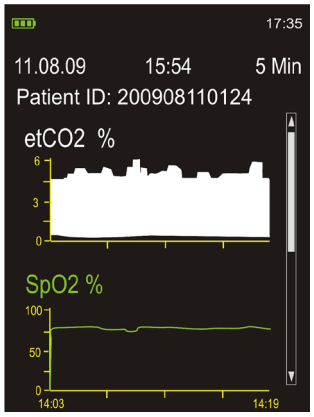
8.1.2.2 Data Management

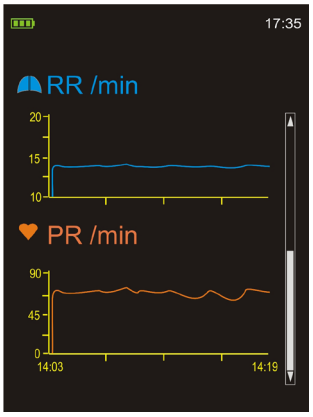
Use the Data Management menu to access the list of stored data sets and stored alarms, to delete all data in the memory or to view the remaining recording time. Retrieve the selected data set by pressing the ↵/⏻ button.

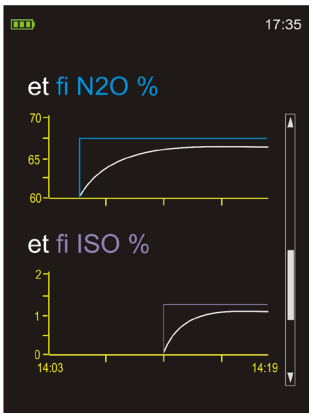


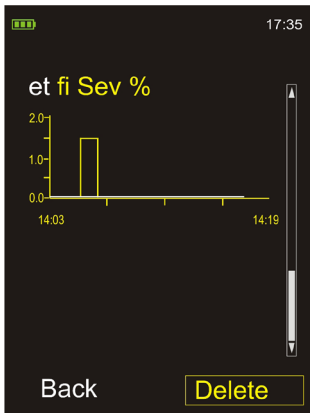


The stored measurements are displayed in graphic form together with the date, start time, duration of the recording and Patient ID. Select “Back” to return to the list of stored data or “Delete” to erase the data set and its corresponding stored alarms.



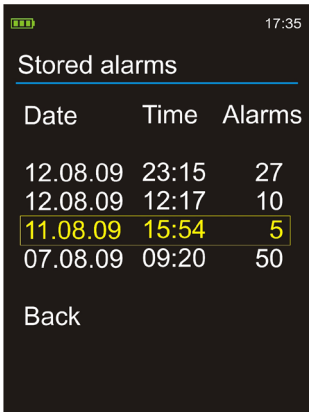


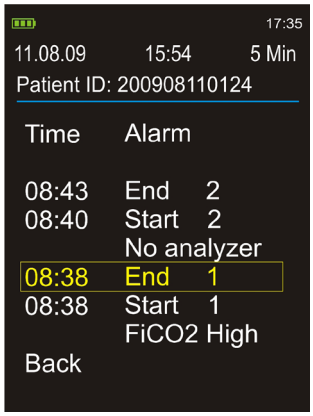




For each stored data set a file with the stored alarms is generated. The stored alarms are displayed as list together with the date, start time, duration of the recording and Patient ID.

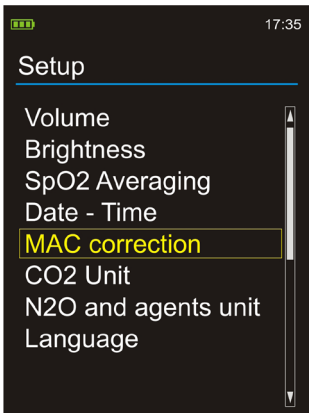
Next to the stored alarm message the start time of the alarm is displayed. Above the start time the time at which the alarm condition stopped is displayed.

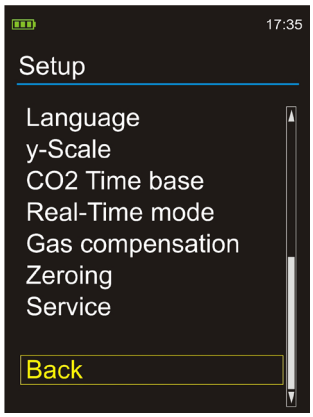




8.1.3 Submenu: Setup

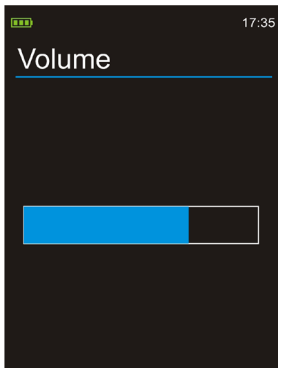
8.1.3.1 General Information





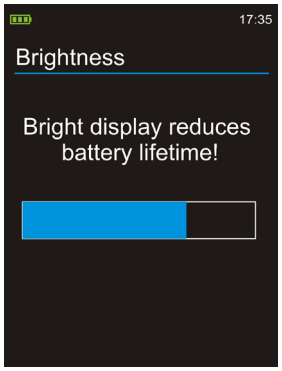
This submenu offers access to various device settings; confirm selection by pressing the ↵/⏻ button.

8.1.3.2 Parameters



Volume

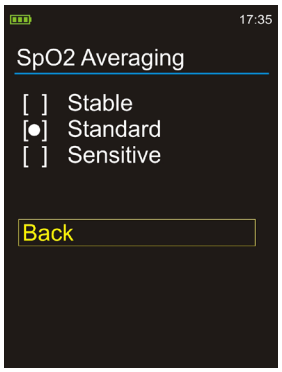
Adjust the pulse tone volume using the ▲▼ buttons. Confirm the new setting by pressing the ↵/⏻ button.



Brightness

Adjust the display brightness using the ▲▼ buttons. Confirm the new setting by pressing the ↵/⏻ button.

Note: Very high brightness settings will shorten the battery life considerably!



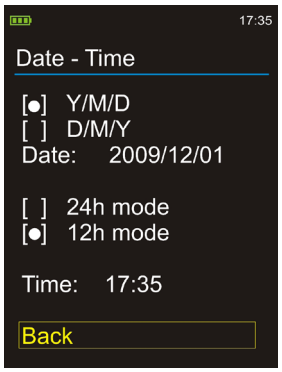
SpO_2 Averaging

Stable: When this setting is selected any strong and sudden variations in data will not immediately affect the reading (data incorporated over time); minor irregularities have little or no effect on the displayed reading.

Standard: Averaging parameters used for this setting are between those of the stable and sensitive settings.

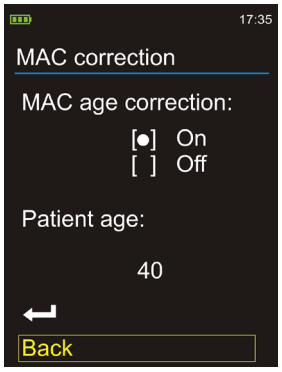
Sensitive: The reading is more sensitive to irregularities but reacts very quickly to any changes in measured parameters.

Refer to Chapter 13 “Technical Specifications“ for further details on the influence of the SpO_2 averaging settings on the SpO_2 reaction time.



Date and Time

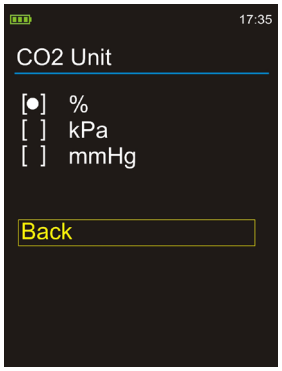
First, select between Y/M/D and D/M/Y mode (respectively 12h mode and 24h mode), then set the date and time. Settings for the date and time are not erased when the batteries are temporarily removed.



MAC correction

By activating the MAC age correction the displayed MAC value is corrected according to the calculation described in chapter 2.1.4.

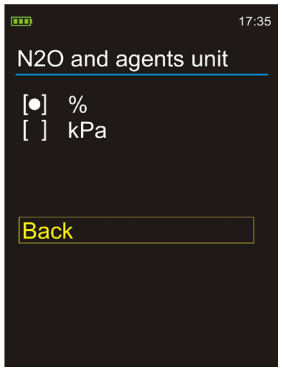
Note: Enter the correct patient age and confirm the value to ensure correct MAC age correction.



CO_2 Unit

By changing the CO_2 unit, the measurement values and default limits of $EtCO_2$ and $FiCO_2$ are converted accordingly.

For conversion to the units kPa and mmHg an automatic barometric pressure compensation is performed.



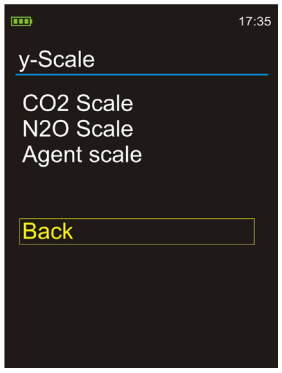
N_2O and agents unit

By changing the N_2O and agents unit, the respective measurement values and default limits are converted accordingly.

For conversion to the unit kPa an automatic barometric pressure compensation is performed.

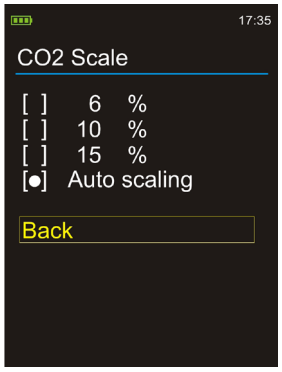
Language

All messages and menus will be displayed in the selected language. The standard language package comprises up to 16 languages. Please refer to the manufacturer for detailed information on the current languages available.



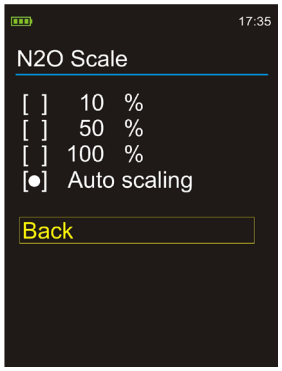
y-Scale

Select the respective y-Scale menu to adjust the amplitude scale of CO_2, N_2O and the anaesthetic agents individually.



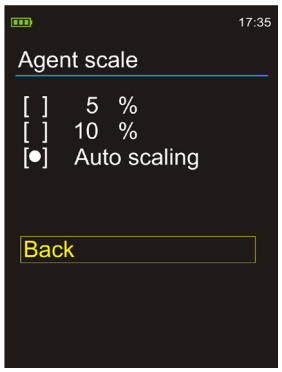
CO_2 Scale

The scale maximum of the capnogram and CO_2 trend can be fixed to 6 %, 10 % or 15 %. Select the option “Auto Scaling” for optimal amplitude scaling of the data. Depending on the selected CO_2 scale, the values will be adjusted accordingly.



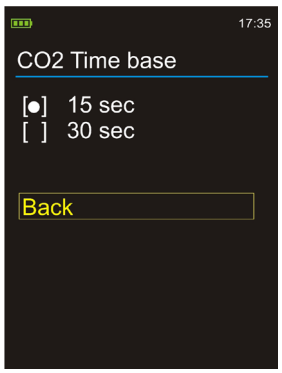
N_2O Scale

The scale maximum of the N_2O trend can be fixed to 10%, 50% or 100%. Select the option “Auto Scaling” for optimal amplitude scaling of the data.



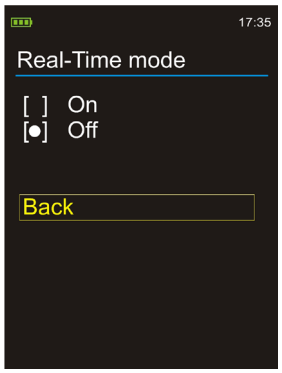
Agent scale

The scale maximum of the anaesthetic agent trend can be fixed to 5% or 10%. Select the option “Auto Scaling” for optimal amplitude scaling of the data.



CO_2 Time Base

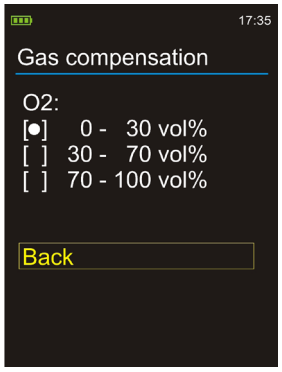
For an optimal time resolution the time base of the capnogram can be adjusted to 15 seconds or 30 seconds.



Real-Time Mode

The Real-Time mode symbol ⇆ indicates that the Real-Time mode is activated. Activation of the Real-Time mode enables visualization and storage of measurement data on a PC.

In this mode the alarm messages and ongoing measurement values of end-tidal and inspired CO_2, N_2O and anesthetic agents, the MAC value, SpO_2, respiration rate and pulse rate are available every 4 seconds at the USB port for download to the PC. For more information please refer to the enclosed Software Manual.

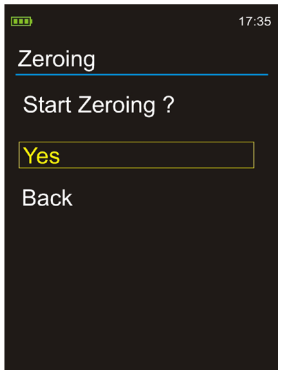


Gas Compensation

The presence of oxygen can cause interference in the CO_2 measurement. These interferences are compensated by setting the range of the O_2 concentration under the menu point “Gas compensation” accordingly.

If the O_2 concentration range is set correctly, the maximum relative CO_2 error will be limited to 1.2%.

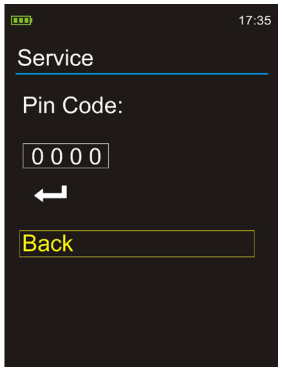
Note: Interference in the CO_2 measurement due to the presence of N_2O is automatically compensated within the IRMA AX+ analyzer. This is not the case if an IRMA CO_2 analyzer is connected to the CapnoTrue®MG.



Zeroing

Zeroing needs to be performed when an offset in $EtCO_2$ and $FiCO_2$ values is observed, when an unspecified accuracy message is displayed or when the airway adapter is replaced.

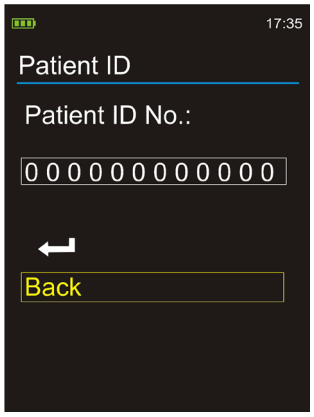
⚠ *Warning: Incorrect zeroing will result in false gas readings. Refer to chapter 11.4 for detailed information.*



Service

The Service submenu is protected by a PIN code; only authorized service personnel can access this menu (Refer to the Service Manual for more information).

8.1.4 Submenu: Patient ID



The CapnoTrue®MG features the possibility of saving a 12 digit patient ID together with every created data file. If the Patient ID is changed via the menu during measurement, the current data file is closed and a new data file with the new Patient ID is opened. A message is displayed to inform the user.

8.1.5 Default Start Settings

Changed settings are in effect only as long as the CapnoTrue®MG remains switched on. Once the CapnoTrue®MG has been switched off, at the next start up, the default settings will be in effect. The start up defaults can be changed in the PIN protected Service Menu. Only authorized service personnel can access this menu.

8.2 Other

8.2.1 Volume Control Shortcut

If the ▲ button is pressed during any monitoring display mode, the volume control screen will open. Adjust the volume using the ▲▼ buttons. Confirm the new setting by pressing the ↵/⏻ button.

8.2.2 Brightness Control Shortcut

If the ▼ button is pressed during any monitoring display mode, the brightness control screen will open. Adjust the brightness using the ▲▼ buttons. Confirm the new setting by pressing the ↵/⏻ button.

8.2.3 Power-Save Mode

The device's display can be turned off to save power and extend battery life. This can be accomplished by pressing and holding the ▼ button. A countdown will start, after which the display will be switched off. The device is now in economy power mode. The pressing of any button will reactivate the display.

9 Adverse affects on performance
9.1 Multigas measurements

Interfering gas and vapour effects

Gas or Vapour	Gas Level vol%	CO_2 Measurement Interference
N_2O [3]	60	CO_2 - [1 & 2], N_2O and agents- [1]
HAL [3]	4	- [1]
ENF, ISO, SEV [3]	5	- [1]
DES [3]	15	- [1]
Xe (Xenon)	80	CO_2: -10% of reading; N_2O and agents- [1]
He (Helium)	50	CO_2: -6% of reading; N_2O and agents- [1]
Metered dose inhaler propellants [3]	Not for use with metered dose inhalers propellants	
C_2H_5OH (Ethanol) [3]	0.3	- [1]
C_3H_7OH (Isopropanol) [4]	0.5	- [1]
CH_3COCH_3 (Acetone) [3]	1.0	- [1]
CH_4 (Methane) [3]	3.0	- [1]
CO (Carbon monoxide) [4]	1.0	- [1]
NO (Nitrogen monoxide) [4]	0.02	- [1]
O_2 [4]	100	CO_2 - [1 & 2], N_2O and agents[1]

Note 1: Negligible interference, effect included in the specifications "accuracy, incl. interfering gases" (refer to Chapter 13)
Note 2: Negligible interference with O_2 concentrations correctly set in the SETUP MENU, effect included in the specifications "accuracy, incl. interfering gases" (refer to Chapter 13)
Note 3: According to the EN ISO 21647:2004 standard
Note 4: In addition to the EN ISO 21647:2004 standard

9.2 SpO_2 Measurement

Physiological conditions, medical procedures, or external agents that may interfere with the monitor's ability to detect and display accurate SpO_2 measurements include:

- Incorrect application of the SpO_2 sensor
- Placement of the SpO_2 sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Excessive patient activity
- Intravascular dyes
- Externally applied colouring agents, such as nail polish
- Failure to cover the sensor site with opaque material in high ambient light conditions
- Venous pulsation
- Dysfunctional haemoglobin, e.g. caused by carbon monoxide intoxication
- Low perfusion

10 Troubleshooting guide
10.1 Error Message – Cause – Corrective Action

Error Message	Cause	Corrective Action
Battery low !	Low battery level at start up results in error message and dysfunction. Critical level during monitoring results in audible alarm and battery indicator to flash yellow. After 3 minutes device switches off.	Replace batteries immediately or connect the external power supply to the AC line.
Device defective !	Defective hardware, e.g. PCB.	Send the device to qualified service personnel.
No SpO_2 Sensor !	No connection to the SpO_2 sensor.	Check sensor connection.
SpO_2 Probe off !	The SpO_2 sensor is connected to the device, a signal was detected and then the finger has been removed/slipped off.	Check that the sensor is correctly attached to the patient.
SpO_2 Sensor fault !	The connected SpO_2 sensor is either defective or not compatible with the device.	Replace sensor.
Excess light !	High ambient light sources near the SpO_2 sensor, e.g. surgical lights.	Shield sensor more effectively from external light.
Bad signal quality !!!	Poor-quality pulse signal, for example as a result of low perfusion.	Check other vital signs to ensure sufficient perfusion. Move the sensor to a different site on the patient or provide more effective monitoring conditions.
CO_2 Overrange !	The measured CO_2 concentration is outside of the specified accuracy range.	Ensure that device is used in an environment with a CO_2 concentration within the specified accuracy range.
N_2O Overrange !	N_2O outside specified accuracy range	Ensure that device is used in an environment with a N_2O concentration within the specified accuracy range.
Anesthetic agent overrange !	At least one agent outside specified accuracy range	Ensure that device is used in an environment with an anaesthetic agent concentration within the specified accuracy range.
Temperature overrange !	Internal temperature outside operating range	Ensure that device is used in an environment with a temperature within the specified operating range.
Ambient pressure overrange !	Ambient pressure outside operating range	Ensure that device is used in an environment with a pressure within the specified operating range.
Zeroing required !	Zero reference calibration required	Perform zeroing (refer to chapter 11.4)
Unspecified accuracy !	Agent identification and concentrations are unreliable	Replace the airway adapter and perform zeroing (refer to chapter 11.4).
No analyzer !	No connection to the mainstream IRMA AX+ analyzer.	Check connection.
Check Adapter !	The mainstream IRMA adaptor is dirty, not positioned correctly etc.	Check airway adapter and replace if required
Analyzer fault !	The mainstream IRMA AX+ analyzer is defective.	Replace IRMA AX+ analyzer.

Data memory full, overwrite? Yes/No	Message is displayed at every startup of device if the memory is full.	Delete files or overwrite.
Zeroing disabled	The IRMA AX+ analyzer / Nomo Adapter is not connected.	Connect the IRMA AX+ analyzer / Nomo Adapter and try again.
	Other causes	Send the device to qualified service personnel.

10.2 Failure – Cause – Corrective Action

Failure	Cause	Corrective Action
No response to the power button	Power button is not fully depressed.	Ensure that the power button is fully depressed.
	The batteries may be missing, discharged, or oriented incorrectly or no power supply is connected.	Install new batteries or connect the power supply to the AC line.
Audible medium priority alarm sounds while the device is off and can not be restarted again	Power supply is disconnected during operation while no batteries are installed. Medium priority audible alarm occurs for 2 minutes whereupon device switches off.	Reconnect power supply immediately or insert battery.
No pulse signal found or the pulse signal cannot be found anymore	Patient has no pulse signal.	Check the patient.
	The incorrect SpO_2 sensor is used.	Check the sensor 'Instructions for Use' to determine if an appropriate sensor is being used and if it is applied correctly.
	SpO_2 sensor or extension cable is defective.	Check the sensor and extension cable connections. Test the sensor on another subject. Try another sensor or extension cable.
	Perfusion may be too low for the monitor to track the pulse.	Check the patient. Test the monitor on yourself. Change the sensor site. Try another sensor.
	Interference due to patient activity may be preventing the monitor from tracking the pulse.	Keep the patient still, if possible. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site.
	The sensor may be too tight, there may be interference due to ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.	Reposition sensor, as necessary.
	Electromagnetic interference may be preventing the monitor from tracking the pulse.	Remove the source of interference.
No pulse tone	Pulse beep volume is off.	Switch volume on.
	Speaker/audio has malfunctioned. Signal is corrupted. The CapnoTrue®MG has stopped functioning.	Contact qualified service personnel.

$EtCO_2$ values are inconsistent	Physiological reasons.	Check the patient.
	Leakage in the system.	Check the tubes and connections to the patient
$EtCO_2$ values are continuously higher or lower than expected.	Physiological reasons.	Check the patient.
	Zeroing or calibration required.	Contact qualified service personnel.

10.3 IRMA AX+ LED Status

Indication	Status	Action
● *Steady green light*	System OK	-
☀ *Blinking green light*	Zeroing in progress	-
● *Steady blue light*	Anaesthetic agent(s) present	-
● *Steady red light*	System Error	check device error message
☀ *Blinking red light at IRMA LED*	IRMA adapter defective	Check IRMA adapter

10.4 Problems with EMI (Electromagnetic Interference)

The CapnoTrue®MG has been tested and found to comply with the limits for medical devices according to: EN 60601-1-2, (second edition) and the Medical Device Directive 93/42/EEC.

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Due to the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of performance of this device. Examples of noise sources in healthcare environments that could cause electromagnetic interference include:

- Electrosurgical units
- Cellular phones
- Mobile two-way radios
- Electrical appliances
- High-definition televisions (HDTVs)

The measurement values of CapnoTrue®MG can be obscured by electromagnetic interference. During such interference measurements may seem inappropriate or the monitor may not seem to operate correctly.

Disruption may be evidenced by erratic readings, cessation of operation or other incorrect functioning. If this occurs, the operating environment should be surveyed to determine the source of disruption and the following actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reposition or relocate the interfering equipment.
- Increase the distance between the interfering equipment and this equipment.

The CapnoTrue®MG will generate, use and radiate radio frequency energy. Failure to follow these instructions may cause harmful interference with other devices in the vicinity.

11 Maintenance

11.1 Maintenance

The monitor requires no routine calibration. If service is necessary, contact qualified service personnel or your local sales representative.

Caution: There are no user-serviceable parts within the CapnoTrue®MG. The cover should only be removed by qualified service personnel.

Caution: The CapnoTrue®MG requires no routine calibration. A basic maintenance plan conducted by qualified service personnel is recommended. Please refer to the Service Manual for detailed information.

11.2 Cleaning

Surface-clean

The CapnoTrue®MG and its accessories should be cleaned on a regular basis. Use a soft cloth dampened with either a commercial, nonabrasive cleaner, or a solution of 70% alcohol in water to clean the device. Lightly wipe the surface of the monitor.

The IRMA AX+ Analyzer and the SpO_2 sensor can be cleaned using a cloth moistened with maximum 70% ethanol or maximum 70% isopropyl alcohol. Remove the disposable IRMA Airway adapter prior to cleaning the IRMA AX+ Analyzer.

Caution: Do not immerse the CapnoTrue®MG or its accessories in liquid.

Caution: Do not spray, pour, or spill any liquid on the CapnoTrue®MG, its accessories, connectors, switches, or openings in the enclosure as this may result in damage to the unit.

Disinfection
Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water to disinfect the device housing.

Caution: Do not autoclave or steam sterilize the CapnoTrue®MG device, or its disposable accessories.

Caution: Do not autoclave or steam sterilize the IRMA AX+ Analyzer

11.3 Testing

Test of the alarm system
In order to trigger an alarm for test purposes during monitoring set the upper alarm limit of SpO_2 or pulse rate below the currently indicated measurement value. The device will react with a visual and audible alarm.

Test of the measurement accuracy SpO_2
The only reliable method of testing the SpO_2 measurement accuracy of the monitor is the clinical validation of the measurement data, indicated by the system monitor with SpO_2 sensor on the basis of a blood gas analysis. During extensive clinical studies, the monitor combined with the approved sensors evidenced the accuracy required. Verify SpO_2 readings at regular intervals with a reference instrument.

Note that a functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.

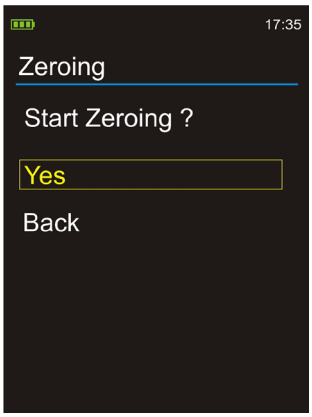
Test of the gas measurement accuracy
The gas measurement module of the CapnoTrue®MG is permanently factory calibrated. Reliable testing of the measurement accuracy of the gas measurement requires the use of a suitable calibration gas mixture. During extensive measurements with calibration gas, the gas measurement unit evidenced the accuracy required.

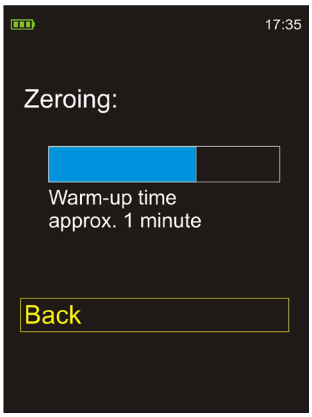
Verify gas readings at regular intervals with a reference instrument.

11.4 Zeroing the multigas monitor
11.4.1 Mainstream CapnoTrue®MG

Zeroing should be performed every time the IRMA airway adapter is replaced, or whenever an offset in gas values or an unspecified gas accuracy message is displayed:

1. First connect a new IRMA airway adapter onto the IRMA AX+ analyzer, without connecting the airway adapter to the patient circuit.
2. Allow 30 seconds for warm up of the IRMA AX+ analyzer after power on or after changing the IRMA airway adapter before proceeding with the zeroing procedure.
3. Ensure that ambient air (21% O_2 and 0% CO_2) is present in the IRMA airway adapter.
4. Select MAIN MENU > SETUP > ZEROING at the monitor.
5. Start the zeroing by selecting “Yes” when the message “Start Zeroing?” is displayed.
6. If zeroing is performed before warm up is completed, a warm up screen is displayed indicating the status of the warm up procedure.





7. Zeroing is started automatically after warm up. The green LED on the analyzer will be blinking for approximately 5 seconds while zeroing is in progress.
8. The message “Zeroing completed !” indicates that the zeroing was successful.

Special care should be taken to avoid breathing near the airway adapter before or during the zeroing procedure. Always perform a pre-use check after zeroing the IRMA AX+ analyzer.

⚠ *Warning: Incorrect zeroing of the IRMA AX+ analyzer will result in false gas readings. A successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2) in the IRMA airway adapter during zeroing.*

12 CapnoTrue®MG PC-Software

With the user-friendly CapnoTrue®MG PC-Software all measurement data, selected alarm limits and alarm messages can be stored on a PC via the USB interface. Here the data can be viewed and patient data added. The file can be printed or exported as CSV file for processing with additional software.

Furthermore the software can be used to display and save measurement values and alarm messages on a PC, parallel to ongoing measurements.

To enable this function the Real-Time mode has to be selected on the device. During this mode the measurement values of end-tidal and inspired concentration of CO_2, N_2O and anaesthetic agents, the MAC value, SpO_2, respiration rate and pulse rate are available every 4 seconds at the USB port for download to the PC.

For more information please refer to the enclosed Software Manual.

13 Technical Specifications

GENERAL

Parameters displayed
- Numerical: End-tidal (et) CO_2 -, N_2O - and anaesthetic agent concentrations, Inspired (Fi) CO_2 -, N_2O - and anaesthetic agent concentrations, MAC value, oxygen saturation (SpO_2), respiration rate (RR), pulse rate (PR)
- Graphical: Capnogram and trends of numerical data (15min/1h /6h)

Indicators
Signal strength and signal quality, pulse amplitude, battery status, alarm mute, pulse tone mute, storage status, Real-Time mode, time

Alarms
- Limits: Adjustable limits for all numerical parameters except for the MAC value
- Alerts: Audible and visual alarms (complies with EN 60601-1-8)

Storing Data
- Communication interface: USB 2.0
- Data memory on device: up to 150 hours in total
- Real-Time mode: Visualise and save numerical parameters every 4 seconds on PC
- PC-Software: CapnoTrue®MG PC-Software (for data download and Real-Time mode)

MULTIGAS ANALYZER

Warm up time
< 10 seconds (concentrations reported and automatic agent identification), 20 seconds for full accuracy

Measurement Range
- $EtCO_2$ and $FiCO_2$: 0 - 15%
- FiN_2O: 0 – 100%
- Hal, Iso, Enf: 0 – 8%
- Sev: 0 – 10%
- Des: 0 – 22%
- Respiration rate: 0 - 150 breaths/min

Accuracy
- $EtCO_2$ and $FiCO_2$ (0 – 10%): +/- (0.2 vol%. + 2% of reading),
- $EtCO_2$ and $FiCO_2$ (10 – 15%): +/- (0.3 vol%. + 2% of reading), +/- (0.3 vol% + 4% of reading.) incl. interfering gases
- N_2O: +/- (2 vol%. + 2% of reading), +/- (2 vol% + 5% of reading.) incl. interfering gases
- Hal/Iso/Enf/Sev/Des: +/- (0.15 vol%. + 5% of reading), +/- (0.2 vol% + 10% of reading.) incl. interfering gases [1]
- Respiration rate: +/-1 digit

Parameter renews
- $EtCO_2$ and Fi of gases: Displayed after one breath and then a continually updated breath average.
- Respiration rate: Displayed after three breaths and then average value updated every breath.

Operation principle
- State-of-the-art, single path, non-dispersive infrared (NDIR) gas analyzer.

Barometric pressure compensation
The total pressure of the gas mixture is estimated by measuring the actual atmospheric pressure in the IRMA AX+ analyzer. For conversion to the units kPa and mmHg an automatic barometric pressure compensation is performed.

Calibration
Manual zeroing recommended when offset in gas

1) The accuracy specification is not valid if more than two agents are present in the gas mixture

values is observed or airway adapter is replaced. No span calibration required.

Rise time (at 10 l/min)
$CO_2 \leq 90$ms

Primary agent threshold
0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15% as long as apnoea is not detected.

Secondary agent threshold
0.2 vol% + 10% of total agent concentration.

Agent identification time
< 20 seconds (Typically < 10 seconds)

Total system response time:
< 1 second

Airway adapter
- Disposable Adult/Paediatric: < 6ml dead space, < 0.3 cm H_2O pressure drop at 30 l/min
- Disposable Infant: < 1ml dead space, < 1.3 cm H_2O pressure drop at 10 l/min

Length of interface
Cable length at IRMA AX+ analyzer of 2.55 m

Water handling
XTP™ windows of the IRMA airway adapter with special features that prevent a decrease in performance when vapour is present.

PULSE OXIMETER

Measurement Range
- SpO_2: 0 - 100%
- Pulse Rate: 20 - 300 beats/min

Accuracy
- SpO_2 [1]: +/- 2% (70 to 100%)
- Pulse Rate: +/- 1 digit (up to 100 beats/min) or +/- 1% (> 100 beats/min)

Parameter renews (see Table)
First displayed value after application:
- SpO_2: Between 3 seconds and 7 seconds, depending on measurement conditions.
- Pulse rate: Between 5 seconds and 8 seconds, depending on measurement conditions.

PHYSICAL CHARACTERISTICS

Display
Active OLED colour graphic display, 262 000 colours, 240 x 320 pixel (42mm x 56mm)

Dimensions
(L x W x H): 15 cm x 7.5 cm x 3.5 cm

Weight
< 400 g (complete device with batteries)

PULSE OXIMETER Parameter renews

Measurement dynamics		Beat to beat min/max	Sensitive min/max	Standard min/max	Stable min/max
SpO_2 [2]	First reaction after	N/A	1 sec	2 sec	4 sec
	Determined value reached after another	N/A	4 sec	8 sec	12 sec
Pulse-rate [3]	First reaction after	1 sec / 7 sec	1 sec / 7 sec	1 sec / 7 sec	1 sec / 7 sec
	Determined value reached after another	N/A	1 sec / 4 sec	1 sec / 6 sec	1 sec / 8 sec

1) As inherent to their functional principle, pulse oximetry measurements underlie statistical spread, therefore only two thirds of the measurement data are within the specific range of +/- ARMS
2) Measured at de-saturation / re-saturation between 96 % and 84 % SpO_2 under favourable measurement conditions. The values can be extended by a bad pulsation strength or motion artefacts.
3) Maximum values are measured with sudden change from 40 to 200 beates/minute and vice versa. The reaction depends on the difference (variance) of the beats among themselves.

POWER SUPPLY

Power may be supplied by battery, rechargeable battery or by AC power supply

4 x Batteries
Alkaline battery (AA / LR6 / AM3 / MN1500 / Mignon), 1.5V, working time with full functionality approx. 4.5 hours

Li-Poly battery, Model No. CT-2500
Li-Poly battery, 3.7V, 2500mAh, charging time approx. 5 hours, working time with full functionality approx. 7 hours

AC power supply, Model No. FW 7660M/06
Medical power supply with option for country-specific input plug
- Input: 100-240V AC / 50-60Hz / 250mA
- Output: 6V DC / 1.4 A

ENVIRONMENTAL CONDITIONS [1]

Operating conditions
10 - 40°C, 15 - 95% R.H. (non-condensing),
60 - 120 kPa (excl. Li-Poly battery [2])

Storage conditions
-20 - 70°C, 10 - 95% R.H. (non-condensing),
60 - 120 kPa (excl. Li-Poly battery [2])

CLASSIFICATION

General
- The device is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- No sterile parts are included.
- Mode of operation: Continuous operation

Construction
Water-resistant construction of class IPX1 (with silicone cover)

Classification (according to MDD 93/42/EEC)
Class IIb

Electrical safety
Class of protection II / Type BF – Type and degree of protection against electrical shock

APPLIED STANDARDS

The applied standards are listed in the directory COMPLIANCE on the CD-ROM provided with the device.

14 Component Lists and Ordering

14.1 Packing List

- CapnoTrue®MG Multigas/SpO_2 Monitor
- IRMA AX+ Analyzer
- IRMA airway adapter (adult/paediatric)
- Reusable SpO_2 sensor (selectable, see order numbers)
- USB data cable
- Power supply (FW7660M/06)
- Power supply adapter (EU and UK plug)
- Li-Poly battery (CT-2500)
- 4 x Batteries (AA Mignon)
- Silicone protective cover
- User manual + PC software (CD-ROM)

14.2 Order Number

CapnoTrue®MG Starter Kit with standard configuration according to the Packing List:

Sensor style	Order number
SoftCap® SC	3090112009-SC
Ear Probe EP	3090112009-EP
SoftCap® Autoclavable SCA	3090112009-SCA
SoftWrap® Sensor W	3090112009-W
SoftCap® Paediatric SCP	3090112009-SCP
SoftFlap® SF	3090112009-SF

Language Version [3]
Please indicate language version when ordering.
- Europe: EN, DE, ES, FR, IT, NL, SE, RU (additional languages available upon request)
- Asian version: EN, CN, JP (additional languages available upon request)

1) Should the device experience condensation it should be stored for more than 24 hours in an environment with relative moisture content below 95%RH (non-condensing).
2) With Li-Poly battery the conditions are reduced to: operating while charging at 0 – 45°C and 86 – 106 kPa storage (1 month) at -20 - 60°C and 86 – 106 kPa
3) Refer to the manufacturer for detailed information on the current languages available.

14.3 Disposables

- IRMA airway adapter (adult/paediatric), P/N 3050121001, Mainstream airway adapter for adult and paediatric use, box of 25
- IRMA airway adapter (infant), P/N 3050121002, Mainstream airway adapter for infant use, box of 10

14.4 SpO_2 Accessories

- SoftCap® Sensor, SC 6500, P/N 1020132001, 3rd generation adult soft sensor, 1.2m silicone cable
- SoftFlap® Finger Sensor, SF 6500, P/N 1020132002, Fingerclip sensor with ambient light shield, 1.2 m long cable, PVC cable
- SoftCap® Sensor, SCP 6500, P/N 1020132300, 3rd generation paediatric soft sensor, 1.2m silicone cable
- SoftCap® Sensor autoclavable, SCA 6500, P/N 3020132101, 3rd generation adult soft sensor, 1.2m silicone cable, ≥ 200 autoclaving cycles
- SoftCap® Sensor autoclavable, SCPA 6500, P/N 3020132118, 3rd generation paediatric soft sensor, 1.2m silicone cable, ≥ 200 autoclaving cycles
- SoftWrap® Sensor, W 6500, P/N 2020132006, wrap sensor, 1.2m silicone cable
- Ear Sensor, EP 6500, P/N 1020132254, Ear sensor, 1.2m long cable, PUR cable, PUR ear hanger
- Extension Cable, XT 6500, P/N 1020132275, 1.2m cable length, PVC cable
- Extension Cable, XT 6501, P/N 1020122058, 2.4m cable length, PVC cable

Additional SpO_2 sensors are available upon request

Other Accessories

- Universal Mounting Kit, P/N 3090122008, V-adapter with female pole-mount thread
- Universal Pole-Mount Adapter, P/N 1020122060, Adapter with vertical and horizontal adjustment
- Carry case, P/N 1020122061, Carrying bag for main unit and sensor, with shoulder strap
- Europe power supply plug, P/N 3090122003, Europe adapter for power supply FW7660M/06
- UK power supply plug, P/N 3090122004, UK adapter for power supply FW7660M/06
- AUS power supply plug, P/N 3090122011, Australian adapter for power supply FW7660M/06

14.5 Replacement Parts

- IRMA AX+ analyzer, P/N 3050132002, Multigas analyzer
- Power supply, FW7660M/06, P/N 3090122002, Power supply for continuous operation of the CapnoTrue®MG and charging of Li-Poly battery, Input: 100-240V AC / 50-60Hz, Output: 6V DC / 1.4A
- Silicone Protective Cover, P/N 3090122006, Protective cover for the CapnoTrue®MG device
- Li-Poly battery, CT-2500, P/N 3090122005, special rechargeable battery for use with the CapnoTrue®MG, 3.7 V / 2500 mAh
- USB Data Cable, P/N 3090122001, Data cable for data transfer between the CapnoTrue®MG device and PC
- CapnoTrue®MG CD-ROM, P/N 4090422001, CD with the CapnoTrue®MG User Manual + PC software